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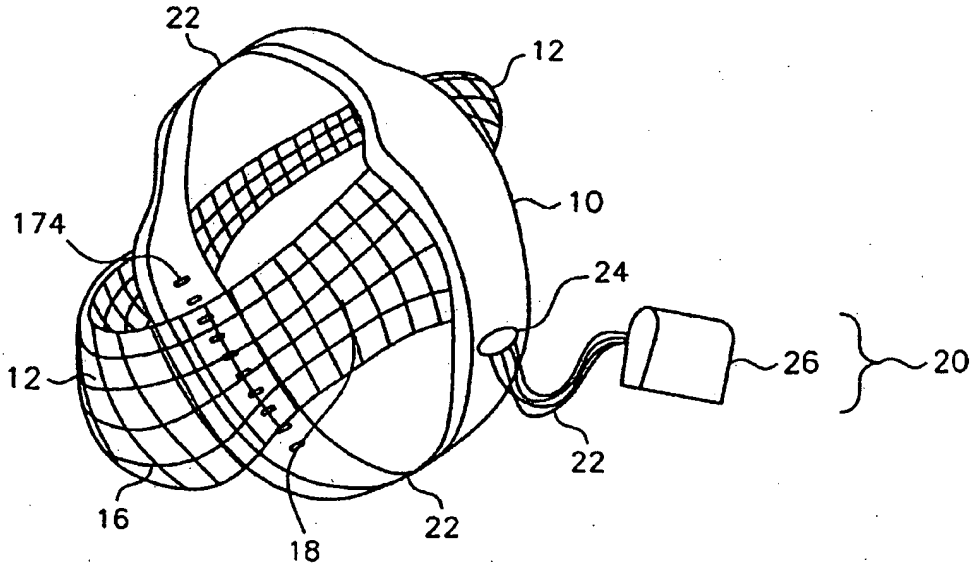
(54) Title: DEVICES AND METHODS FOR ASSISTING NATURAL HEART FUNCTION



(57) Abstract: Devices and methods for treating a diseased heart including devices and methods for remodeling or reconfiguring a shape of a diseased heart, assisting in function of a diseased heart, and stabilizing such devices on a diseased heart. In some embodiments, the devices and methods include one or more segments for changing a shape of the heart or a portion thereof, and methods for using such devices and methods.

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DEVICES AND METHODS FOR ASSISTING NATURAL HEART FUNCTION

FIELD OF THE INVENTION

This invention relates to devices and methods for assisting in the activation and operation of a living heart, including structures for mechanically deforming cardiac tissue such that the circulation of blood is maintained and assisting in movement of cardiac tissue during the cardiac cycle.

BACKGROUND OF THE INVENTION

Various methods and devices have been proposed for altering the shape of a diseased heart chamber. None have yet proven practical and effective. The present invention addresses a number of new methods and devices to improve, or avoid the deficiencies of prior methods and devices.

SUMMARY OF THE INVENTION

The present invention is directed to devices and methods for reconfiguring one or more chambers of a natural heart to reduce wall tension on the natural heart walls and/or for reconfiguring one or more structures such as valves, muscles, tendons or other structures of the natural heart, and/or to alter, improve or correct the anatomical structure of the natural heart so that the natural heart can function more efficiently or to correct other problems of the heart. In several embodiments, the segment or segments are adapted to lie adjacent the external surface of the natural heart in an unrestrained position, to cause an inward displacement of one or more locations of the external surface of the natural heart, and to prevent the natural heart from returning to the unrestrained position. In other embodiments, the segment or segments are internal to one or more chambers of the natural heart.

In one or more embodiments, the devices include one or more main segments that encircle a portion of or the entire natural heart at a selected location. The segments of the present invention are configured to provide differential pressure along a selected location of one or more chambers on the surface of the natural heart or a portion thereof by including rigid, semi-rigid and flexible segments or portions thereof, at different locations of the segment or segments of the devices on the natural heart, thereby displacing one or more chambers of the natural heart or a structure thereof (such as a heart valve, muscle, or tendon) and to prevent it from returning to its unrestrained configuration. Several elements such as the main segments or stabilizer/reconfiguration segments can be interchanged and combined with one another to form a

effectiveness of the heart, and devices and methods for treating cardiomyopathies on a long term basis.

In one embodiment, the present invention provides devices and methods for treating cardiomyopathies that do not require removal of any portion of an existing natural heart. In another embodiment, the present invention provides devices and methods for treating dilated cardiomyopathies that directly reduce the effective radius of a chamber of a heart in systole as well as in diastole.

The devices of the present invention can be fixed to the heart in a manner which keeps the device in a desired location. In one or more embodiments, the present invention includes a stabilization system which employs rigid, semi-rigid, flexible belts or straps or harnesses. In one embodiment, the stabilization system or remodeling elements provide a site onto which cardiac transceivers or pacing leads may be secured which allows adding a plurality of transceivers or pacing leads to the heart at whatever spacing and arrangement may be desired.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1A is a top cross-sectional view of a convex main segment on a heart;

Fig. 1B is a top cross-sectional view of a flat main segment on a heart;

Fig. 1C is a top cross-sectional view of a concave main segment on a heart;

Fig. 1D is a perspective view of a convex main segment on a heart;

Fig. 1E is a perspective view of a flat main segment on a heart;

Fig. 1F is a perspective view of a concave main segment on a heart;

Fig. 2A is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in an open configuration;

Fig. 2B is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration;

Fig. 3 is a perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration on a heart;

Fig. 4 is a top perspective view of a heart remodeling clasp including two main segments and apical and atrial segments, in a closed configuration on a heart;

Fig. 5A is a side perspective view of a main segment with a stabilizer/reconfiguration segment to support a valvular annulus of a heart;

Fig. 15A is a side cross-sectional view of a main segment with protrusions on the main segment;

Fig. 15B is a side cross-sectional view of the device in Fig. 15A in contact with heart tissue;

Fig. 15C is a top cross-sectional view of a main segment with moveable protrusions on the main segment;

Fig. 15D is a top cross-sectional view of the device in Fig. 15C in contact with heart tissue;

Fig. 16 is a perspective view of a main segment with moveable protrusions on a surface of the main segment;

Fig. 17 is a perspective view of a main segment including a multi-segmented, self-orienting plate;

Fig. 18A is a perspective view of an assembled main segment including multi-segmented, self-orienting plates;

Fig. 18B is a perspective view of one plate attached to a main segment, with movement of the plate shown by dotted lines;

Fig. 18C is an enlarged perspective view of one plate shown in Fig. 18A;

Fig. 19 is a perspective view of the device in Fig.18A having a shell;

Fig. 20A is a perspective view of an alternative embodiment of a plate of a multi-segmented, self-orienting main segment;

Fig. 20B is a perspective view of multiple plates of Fig. 20A;

Fig. 20C is a perspective view of a main segment including multiple plates in Figs. 20A and 20B;

Fig. 21A is a perspective view of another embodiment of a plate of a multi-segmented, self-orienting main segment;

Fig. 21B is a perspective view of a main segment including multiple plates in Fig. 21A;

Fig. 22 is a perspective view of part of a main segment including wire reinforcements;

Fig. 23 is an end view of main segment;

Fig. 39 is a perspective view of the device of Fig. 38 partially inserted into the apical portion of a ventricle;

Fig. 40 is a perspective view of one embodiment of deployment of the spring mechanism from the sheath shown in Fig. 38;

Fig. 41 is a top cross-section view of another embodiment of a spring mechanism in a ventricle and connected to two heart remodeling main segments;

Fig. 42 is a top cross-section view of another embodiment of a spring mechanism outside a ventricle and connected to two heart remodeling main segments;

Fig. 43 is a side cross-section view of another embodiment of a spring mechanism within a ventricle;

Fig. 44 is a top cross-section view of Fig. 43 and including certain structure of the heart;

Fig. 45 is a side cross-section view of another embodiment of the spring mechanism in a U-shaped configuration in a ventricle;

Fig. 46A is a perspective view of positioning of a tether connected to a main segment around a portion of the heart;

Fig. 46B is a side cross-section view of the tether of Fig. 46A surrounding a portion of the heart;

Fig. 47A is a perspective view of the main segment and attached tether in Fig. 46A with the main segment in place on the posterior of the heart;

Fig. 47B is a side cross-section view of the main segment and tether on a heart shown in Fig. 47A;

Fig. 48A is a perspective view of two main segments and one or more tethers being placed around a portion of the heart;

Fig. 48B is a side cross-section view of the main segments and one or more tethers on a heart shown in Fig. 48A;

Fig. 49A is a perspective view of two main segments and one or more tethers in place on a heart;

Fig. 49B is a side cross-section view of the main segments and one or more tethers on a heart shown in Fig. 49A;

Figs. 60A are perspective and top, respectively, views of a pin used to secure a clip to a stabilizer/reconfiguration segment;

Fig. 61 is a partial perspective view of the device in Fig. 55;

Fig. 62 is a partial perspective view of the device in Fig. 55;

Fig. 63A is a top perspective view of the device of Fig. 55 including two main segments with pads attached thereto and the stabilizer/reconfiguration segments in Figs. 56 and 58 attached thereto;

Fig. 63B is side perspective view of the device shown in Fig. 63A;

Fig. 64A is a side view of a device in Fig. 55 including two main segments having multi-segmented plates thereon;

Fig. 64B is a perspective view of the device in Fig. 64A;

Fig. 65 is a top cross-sectional view of multiple positions of main segments on a heart;

Fig. 66 is a top view of the device in Fig. 65 placed on a heart and including two stabilizer/reconfiguration segments;

Fig. 67 is a side view of a main segment and a stabilizer/reconfiguration segment on a heart;

Fig. 68 is a perspective view of a U-shaped remodeling device including multiple stabilizer/reconfiguration segments and pacing leads;

Fig. 69A is a cross-sectional view of a main segment encased in a suturable material;

Fig. 69B is a cross-sectional view of a main segment encased in a suturable material;

Fig. 70 is a perspective view of the device in Fig. 69 A and having one large stabilizer/reconfiguration segment and pacing leads;

Fig. 71 is a perspective view of the device in Fig. 69 and having multiple relatively narrow stabilizer/reconfiguration segments and pacing leads;

Fig. 72 is a cross-sectional view of a ball snap clamping mechanism used to attach a stabilizer/reconfiguration segment to a main segment;

Fig. 73A is a cross-section view of placing an umbrella-like anchored tensioning device in a catheter in a ventricle;

Fig. 73B is a cross-section view of the insertion of the anchored device in Fig. 73A;

Figs. 85A-85D are perspective views of rigid segments to be placed in the sheath in Fig. 83 to form a heart remodeling device;

Figs. 86A-D are side cross-section views of placing multiple interlocking segments in the sheath in Fig. 83;

Fig. 86E is a side view of interlocking rigid segments in Figs. 86A-D;

Fig. 86F is a cross-section view of the device in Fig. 86D and having a final segment encased in a sheath in place on an end of the device;

Figs. 86G-H are cross-section views before and after, respectively, interlocking the final segment in Fig. 86F into place;

Fig. 87 is a perspective view of another embodiment of a main segment the curvature of which can be changed;

Fig. 88 is a perspective view of the individual blocks and pins comprising the device in Fig. 87;

Fig. 89 is a side cross-section view of a main segment including the structure in Fig. 87;

Fig. 90 is an alternative embodiment of the mechanism in an end block of the device in Fig. 89, for changing the curvature of the main segment;

Figs. 91A-B are a side cross-section views of another embodiment having a single cable for changing the curvature of a main segment, in straight and curved positions, respectively;

Figs. 91C-D are side cross-section views of another embodiment having two cables for changing the curvature of a main segment, in straight and curved positions, respectively;

Figs. 92A-B are side cross-section views of another embodiment having one cable for changing the curvature of a main segment including one or more notched edges;

Figs. 93A-B are perspective views of a series of telescoping segments in curved, and in curved and shortened, respectively, positions;

Fig. 94 is a perspective view of another embodiment for changing the length of a segment including telescoping elements;

Fig. 95 is a cross-section view of a series of telescoping elements having a slightly longer and narrower configuration;

Figs. 106A-C are cross-section views of several embodiments of a main segment including an expandable membrane between an inner surface and an outer surface of the main segment, or for moving an inner surface of the main segment relative to an outer surface of the main segment;

Fig. 107 is a cross-section views of another embodiment of a main segment including an screw mechanism for moving an inner surface of the main segment relative to an outer surface of the main segment;

Fig. 108 is another embodiment of the device of Fig. 108 including a rotatable cable for advancing the screw;

Figs. 109A-B are side cross-section views of a main segment including a lever operated by a pull cord for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Figs. 110A-B are side cross-section views of a main segment including another embodiment of a lever operated by a screw cable for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Figs. 111A-B are side cross-section views of a main segment including a hydraulic bellows for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Figs. 112A-B are side cross-section views of a main segment including a hydraulic piston for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Figs. 113A-B are cross-section views of another embodiment of a main segment including an expandable fluid between an inner and outer surface of the main segment, for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Figs. 114A-B are cross-section views of another embodiment of a main segment including movable screw operated shims between an inner and outer surface of the main segment, for moving an inner surface of the main segment relative to an outer surface of the main segment, in closed and open positions, respectively;

Fig. 115 is an end view of another embodiment of an apical stabilization cap;

Figs. 134-137 are perspective or side views of another embodiment of the a heart remodeling device and a remote adjusting mechanism, including a clamping mechanism;

Fig. 138 is an enlarged side view of a portion of a main segment having three purse string or cable holes;

Fig. 139 is an enlarged perspective side view of the clamping mechanism in Fig. 138;

Fig. 140 is an enlarged perspective view of the clamping mechanism shown in Fig. 138;

Figs. 141-142 are side and perspective views of another embodiment of a main segment;

Fig. 143 is an enlarged view of the main segment of Figs. 141-142 on a rigid rod;

Fig. 144 is a perspective view of a main segment and a stabilizer/reconfiguration segment on a heart;

Fig. 145 is perspective view of the device in Fig. 144 on a heart with the posterior portion of the device in partial phantom lines;

Fig. 146 is a top view of the base of a heart, with the device in Fig. 145;

Fig. 147 is a perspective view of two main segments and two stabilizer/reconfiguration segments attached to the main segments;

Fig. 148 is a top view of the device on the heart shown in Fig. 147 where the heart wall is enlarged below the stabilizer/reconfiguration segments;

Fig. 149A is a perspective view of another embodiment of a stabilizer/reconfiguration segment;

Fig. 149B is a perspective view of another embodiment of a stabilizer/reconfiguration segment;

Fig. 150 is a side cross-section view of a heart fitted with a stabilizer/ reconfiguration segment to support a valvular annulus of a heart;

Fig. 151 is an enlarged perspective view of a portion of a main segment including a sheath and stabilization protrusions;

Fig. 152 is an enlarged perspective view of another embodiment of a main segment including a covering sheath;

Fig. 153 is a cross-section view of the main segment of Fig. 152 with stabilization protrusions;

Fig. 169 is a cross-section showing one end of second main segment threaded through an end of the tether or guide wire before placement of the second main segment on an anterior portion of the heart;

Fig. 170 is a cross-section showing a second end of a tether threaded through a second end of the second main segment before placement of the second main segment on the posterior portion of the heart;

Fig. 171 is cross-section view of the device in Fig. 170 on the heart;

Fig. 172 is a perspective view of a heart with one side of Velcro® fastener having alternating elastic strips, attached to the heart tissue;

Fig. 173 is an enlarged perspective view of a main segment with a second side of a of Velcro® fastener having alternating elastic strips attached thereto; and

Fig. 174 is a cross-section of a heart wall and an attached structure (such as a main segment), wherein the structure is attached with a Velcro® fastener having alternating sections of elastic material.

DETAILED DESCRIPTION OF THE INVENTION

The invention is described with reference to the drawings. The figures of the drawings are illustrative rather than limiting and are included to facilitate the explanation of the invention.

Remodeling Support Device

The invention provides a segment that supports and reconfigures the heart. As shown in Figure 1A, a main segment 10 can be modeled to a heart 1 having actual human cardiac heart failure (CHF) dimensions. Preferably, the main segment 10 is configured and positioned on the heart to provide a contact pressure of about 1.4 to about 0.7 times (+/-0.2) the cavitary pressure.

Main segment 10 of the invention can have many differing shapes, depending, for example, on the condition being treated and the size and shape of the heart. The cross section of the segment can have, for example, a convex shape toward the heart (as shown by main segment 10 in Fig. 1A), flat shape (as shown in Fig. 1B as main segment 11), swan shape (as shown in Fig. 12B and 13B), elliptical shape, concave shape (as shown by main segment 12 in Fig. 1C), or a combination thereof. Figs. 1D, 1E, and 1F show main segments 11 of Figs. 1A, 1B, and 1C, respectively, placed on a human heart 1.

In addition, main segment 10 can have, for example, an O-shaped configuration such as

Preferably, stabilizer/reconfiguration segment 12 can be placed without use of cardiopulmonary bypass, without opening any cardiac chamber, and on a beating heart. Central anchoring of the stabilizer/reconfiguration segment 12 to a ventricular remodeling clasp including main segment 10, or other structure fixed to the ventricular wall, is expected to render the resulting repair more durable, better control valve shape, and be able to have an option of including a step of manipulating papillary muscle base position.

Figs. 5A and 6-11B illustrate stabilizer/reconfiguration segment 12 for stabilizing main segment 10 on heart 1 and/or reconfiguring a portion of heart 1 that supports the valvular annulus of heart 1, directly or indirectly, by fitting around and supporting an outer margin of the junction between the atrium and ventricle, and/or the region thereof, of either the left or right side of the heart. In one embodiment, stabilizer/reconfiguration segment 12 exerts force upon the epicardium of the heart overlying the region of the junction between the left or right atrium and the ipsilateral ventricle (including the contiguous left or right atrial wall, and/or the contiguous left or right ventricular wall, and the coronary arteries and cardiac veins in the region), so that force is transmitted through these structures to the parts of the mitral or tricuspid annulus supporting the mural leaflets (posterior leaflet of the mitral valve and/or both the anterior and posterior leaflet of the tricuspid valve).

Figs. 12A, 12B, 13A, 13B, 14A and 14B illustrate a device including main segment 10 having portions stabilizer/reconfiguration segment 12, 10a, or 10c that supports the base of one or more papillary muscles of either the mitral and/or tricuspid valve. In one embodiment, the device according to the present invention exerts force upon the epicardium overlying the region of the base of the papillary muscles in either ventricle.

It should be appreciated that each of the elements of the invention can be combined to achieve a desired outcome. For example, a structure intended to remodel the mitral valve may be mutually anchored to a structure intended to remodel the tricuspid valve.

Main segment 10 can be open-shaped, such as a ring, band, or collar structure, designed to fit around and support the outer margin of either (i) the junction between the atrium and ventricle and/or a region thereof and/or (ii) a portion of the ventricular wall overlying papillary muscle bases, of either the left or right side of the heart. Main segment 10 can be designed to be connected and supported at either end by attachment to one or more relatively stationary structures.

Main segment 10 can also have one or more portions such as extension segments 10a

mesh (shown for example in Figs. 69a, 69b, 153, 154, and 155), or a combination thereof. In one embodiment, heart contacting surface 27 may be a fluid filled (e.g., gel filled) or 'potting' filled pad, or a surface studded with bumps 28 or beads 29, as shown in Figs. 15A, 15B, 15C, 15D and 16. Figs. 15A, 15B, 15C, 15D, and 16, illustrate a cross section or perspective views of main segment 10 and/or stabilizer/reconfiguration segment 12 having bumps 28. In one embodiment, bumps 28 or beads 29 are roughly hemispheric or semi-hemispheric, fixed projections having a diameter of about 2 to about 2.5 mm, that are spaced about 2 to about 2.5 mm from one another, as shown in Figs. 15A and 15B. Surface 27 may also have, for example, beads 29 that float, i.e., are attached to the surface and are movable with respect to the surface, as shown in Figs. 15C and 15D . Preferably the moveable beads 29 have a diameter of about 1.5 to 2 mm and are tethered about 2.5 to about 3 mm apart. As shown in Figs. 15A, 15B, 15C, and 15D, main segment 10 and/or stabilizer/reconfiguration segment 12 may be brought into contact with a section of natural heart 1 that has a traversing coronary artery 31 near the surface. Artery 31 moves slightly to nestle between beads 29 or bumps 28 due to its own intrinsic mobility. In the embodiment with floating bumps 28 or beads 299, bumps 28 and beads 29 may also move to accommodate positioning of artery 31.

As shown in Fig. 7, the stabilizer/ reconfiguration segment 12 can be formed of a mesh framing 16 having openings 18. Mesh framing 16 is flexible, rigid, or a combination thereof. Factors determining the desired flexibility or rigidity of the stabilizer/reconfiguration segment 12 include valve remodeling, facilitating coaptation of mural and non-mural leaflets, countering displacement of papillary muscle bases, and minimizing cyclic compressive or tensile stress at heart-contacting surfaces. Stabilizer/reconfiguration segment 12 can be made of, for example, a fabric material such as a porous or mesh material.

Stabilizer/reconfiguration segment 12 can also include, as illustrated in Fig. 10B, one or more bars or stays 17 connected to one another via one or more strings or cables 22. Fig. 10A illustrates that in embodiments where stays 17 are not used, adjustment of stabilizer/reconfiguration segment 12 may result in uneven tightening of the drawstrings. In one embodiment, each stay 17 can be identical in size and shape, as shown in Fig. 10B, or one or more of the stays 17 can have different sizes and shapes to optimize stability and/or support, such as stay 17a illustrated in Fig. 11A . Stays 17 can be rigid, semi-rigid, or a combination thereof. In addition, stays 17 can be curved, straight, or a combination thereof, to accommodate the size and shape of the heart.

As shown in Fig. 7, main segment 10 can be positioned and/or stabilized adjacent the

(3) a rigid collar or ring, approximately 'C' shaped, contoured to fit the outer surface of the left or right atrioventricular groove, that is fixed anteriorly and posteriorly to the members of an extracardiac remodeling clasp (Fig. 9);

(4) a rigid collar or ring, such as described in (3) above, that has an extension (10b) attachable to a stabilizer/reconfiguration segment 12 intended to lie adjacent at least part of the external surface of the wall or the left and/or right ventricle and/or atrium (Fig. 9);

(5) a ring, approximately 'C' shaped, contoured to fit the outer surface of the left or right atrioventricular groove, that is fixed anteriorly and posteriorly to the members of an extracardiac remodeling clasp including at least one main segment 10, of which some portion(s) is/are substantially flexible and other portion (s) is/are substantially rigid (as shown in Fig. 9);

(6) a rigid, flexible, or part-rigid, part-flexible ring, band, or collar, such as described in (1-5) above, of which the heart-contacting surface is a conforming cushion made of a fluid (e.g., gel) or 'potting' filled membrane sac;

(7) a rigid, flexible, or part-rigid, part-flexible ring, band, or collar, such as described in (1)-(5) above, of which the heart-contacting surface is a conforming cushion made of a soft solid polymer;

(8) a rigid collar or ring, such as described in (1)-(4) above, for which length can be adjusted in one or more dimensions by means of articulating, telescoping members (Figs. 11A and 11B);

(9) a collar or ring, such as described in 8 above, for which telescoping members are controlled by traction via a sheathed string or cable (such as string/cable 22 shown in Figs. 11A and 11B);

(10) a flexible cord or band, such as described in (1)–(9) above, for which length can be adjusted by traction on one or more enclosed cords or cables (such as cable 22 shown in FIG. 11A and 11B; in a purse-string fashion in Figs. 10A and 10B);

(11) a cord or band, such as described in (10) above, in which the enclosed cord or cable length is controlled by traction on sheathed extensions of the cord or cable;

(12) a part-rigid, part-flexible ring, such as described in (5) above, for which length may be adjusted by one or more of the mechanisms described in (8-10);

(13) a ring, collar, or band, such as described in (1) – (12) above, that is fixed to, and stabilized by, a flexible band that circumscribes at least part of the length of the opposite side of

independent such that a plate 170 or part of a plate 170 may pivot if such a configuration is needed to maintain local tangent conformity to the surface of the natural heart.

A cross-section of the locally-rigid frame on which plates 170 are mounted can be, at least in part, arcuate or circular, and plates 170 can be mounted on the frame without axial fixation, such that the plates may rotate. By having very low torsional rigidity in the long axis of plates, different areas of plates 170 may rotate independent of each other. One advantage is that transverse (meaning perpendicular to the local long axis of the mounting frame) orientation of plates 170 adapts, because of the balance of moments imposed by reaction of the heart surface, to tangency with that surface resulting in substantial or full surface contact.

Fig. 17 also illustrates an embodiment of a plate 170, a plate spacer 171, and a frame, shown as rod 172, constructed in accordance with principles of one aspect of the present invention. In one embodiment, plate 170 illustrated in Fig. 17 has a slit or opening 173 adapted to accommodate plate spacer 171. Plate 170 can have any desired shape depending on the particular location of the natural heart or portion thereof to which it is to be applied. In one embodiment, plate 170 is convex in shape, where the convexity is toward a surface of the natural heart or portion thereof to which plate 170 is applied.

As shown in Fig. 18A, 18B, 18C, one or more segment plates 170 can be positioned on rod 172. Segment plates 170 can include segment plate spacers 171 and can be attached to rod 172, for example, by a snapping action. In one embodiment, plates 170 can be fixedly attached to rod 172 such that the plates 170 do not pivot or rock with respect to rod 172. In a preferred embodiment, shown in Fig. 18B, plates 170 are removably attached to rod 172 such that plates 170 can pivot or rock and remain tangential with respect to the surface of natural heart 1. It should be appreciated by those of ordinary skill in the art that plate 170 can be attached to the frame by conventional means, such as by a ferrule coupling or pressure fitting, etc.

In another embodiment of the present invention, plate 170 can also be partially or fully covered by a shell 190, as illustrated in Fig. 19. The shell 190 serves to protect the patient against infection (e.g., by excluding tissue fluid from poorly-exchanged spaces where it would be a culture medium for bacteria) and also protects the heart surface against erosion by discontinuities between plate components. Preferably, shell 190 is composed of a biocompatible flexible, low-durometer polymer. In one embodiment, shell 190 includes a gel surrounding plates 170. In another embodiment, shell 190 is a solid shell formed of a uniform polymer material.

Plates 170 also can be formed from one or more plate wires 200, as shown in Figs. 20A,

segment (10), all of which are sized for the particular dimensions of heart 1. Atrial segment 260, as illustrated in Fig. 26, can be configured for placement adjacent the atrial wall. As shown in Fig. 27, apical segment 270 can be configured for placement adjacent the ventricular apical wall. The outer surfaces of atrial and apical segments 260 and 270 shown in Figs. 26 and 27 can be covered by a textured material, such as, for example, a velour, porous (such as a mesh) fabric, to facilitate tissue ingrowth and fixation.

Fig. 28 illustrates an embodiment of a main segment 10 having a central spine 286 that is configured for placement adjacent a portion of the ventricular wall and atrioventricular junction and extensions 281 and 282 that are either straight or arcuate, depending on the shape of heart 1. More specifically, main segment 10 illustrated in Fig. 28 includes extension 281 having a connector portion 287 (such as a hollow section for releasably accommodating atrial segment 260, as shown in Fig. 26) for connection to apical segment 260; a curved section 283 convex to the heart, approximating a circular arc of about 60 to 90 degrees and intended to lie adjacent the atrioventricular junction, preferably having a radius of curvature ranging from about 5 to about 15 mm; a ventricular shoulder section 284 concave toward the heart, having a circular arc, generally having a radius of curvature of about 10 to about 30 mm, and generally extending about 60 to about 90 degrees; a main section 285 that is approximated by a circular arc (for example, having a radius of curvature of about at least about 100 mm or greater) or an elliptical arc (having a major hemi-axis of at least about 100 mm or greater); and a connector 288 (such as a hollow section for releasably accommodating apical segment 270 as shown in Fig. 27) for connection to apical segment 260.

Figs. 29 and 30 illustrate embodiments of extensions 281 and 282 for connection to the atrial segment 270 and apical segment 260, respectively. In a preferred embodiment, extensions 281 and 282 are telescoping and include indexed (e.g., ball and socket or ratchet) or continual sliding adjustment mechanisms. Alternatively, extensions 281 and 282 can be side-by-side interlocking grooves that provide flexural stability. Extensions 281 and 282 may be circular or non-circular in cross-section. Straight extensions are preferred, as the degree of telescoping does not impose any change in the relative angulation of the two ends of the complete rod assembly. If extensions 281 and 282 are curved, the degree of combined (between both atrial segment 260 and main segment 10, and between apical segment 270 and main segment 10) telescoping without unacceptable change of end angulation may be limited.

Generally, closed, non-communicating spaces that would contain stagnant tissue fluid should be avoided. This can be accomplished, for example, by open-sided, outside telescoping

location. This dimension, as well as the radius of curvature for the plate 170 surface that is to contact the heart, is computed from heart diameter, wall thickness, geometric values, and the intended epicardial to cavitary pressure ratio and extent of intended radius reduction.

In the direction that is perpendicular both to the local frame and to the local heart surface, the dimension of rod 172 and plate 170 is sufficient to effect sufficient flexural rigidity across the width of the completed plate 170 to prevent substantial deformation under expected forces when mounted on rod 172 and used to deform the heart as intended clinically. After assembly, the entire plate 170, spacer 171 (if used), rod 172 assembly is covered with a low durometer polymer, that is biocompatible, such as a polyurethane or a silicone rubber, as in Figs. 20c and 31.

The present invention reduces or eliminates non-tangential contact between plates of a ventricular geometric remodeling device and the ventricular epicardial surface. Consequences of such non-tangential contact are mediated by excessive pressure, and include local subepicardial tissue ischemia, coronary artery occlusion and/or damage, and possible erosion into the surface. The present invention also reduces or eliminates the attendant risk of excessive localized pressure which may cause on of the above consequences.

Plates 170 are different from standard plates 550 (such as that shown in Fig. 31 or 55 below) that are fixed to the support structure of a remodeling device (such as a heart remodeling device such as the CardioClasp) in that the plates 170, upon contact with the epicardium, rotate to the lowest-energy (most stable) position, preferably tangent to a surface of heart 1.

An advantage of the invention is that the lowest-energy (most stable) position, because of the structure of plate 170 mounting, is tangent with the epicardium, rather than a fixed orientation to the frame of the device, which would risk edge effects and excessive contact pressure between the remodeling device and heart 1.

Variations of the invention include:

(A) An assembly similar to that shown in Figs. 19, 20C, 21B, 22 and 31 (all of which may include a low-durometer polymeric filling, 'potting', or fluid such as a gel), may also be used but without the low-durometer polymeric filling, 'potting', or fluid (e.g., a gel).

(B) Plates 170 (such as in Fig. 17) made of a low-durometer polymer, such as a polyurethane or a silicone rubber, that is reinforced by embedded wire, either a multitude of wire loops or links of coiled wire. In one embodiment, the wire reinforcement provides sufficient rigidity of the surface in the direction perpendicular to the long axis of plate 170. Plates 170

equal and opposite, near-equality in energy storage and release means that the pressure effect will be the same. That is, spring mechanism 327 will reduce pressure within the ventricle by a numerically near-equal amount in systole and in diastole, at equivalent ventricular size. The pressure decrement will be the same in early systole as in late diastole, in mid-systole as in mid-diastole, and in late systole as in early diastole. When the wall moves inward with contraction, spring mechanism 373 is also deformed inward. This exerts an outward force on the wall both during contraction and relaxation that is determined principally by the instantaneous ventricular circumference. The relationship between instantaneous circumference and pressure decrement is dependent on the characteristics of spring mechanism 327 such as the effective spring constant if its structure renders it linear in action, its tangent spring constant at each level of deformation otherwise, and its resting configuration. The natural outward force of the ventricle, simultaneous size and shape of the ventricle as well as the spring constant determine the absolute amount of pressure decrement, that is, the difference in chamber pressure from what it would be if the spring mechanism were absent.

Spring mechanism 327 can be used for patients who have symptoms or risks associated with decreased compliance of the ventricles during filling. This is generally manifested by increased pressure in the ventricle(s) at the end of filling (elevated left or right ventricular end-diastolic pressure, LVEDP or RVEDP), which in turn leads to elevated left or right atrial pressure and then to elevated pressure in the veins draining the lungs (pulmonary veins) or the veins draining the body (systemic veins), respectively. Symptoms of a left sided problem include shortness of breath and risks are dangerously low oxygen saturation because of fluid in the lungs (pulmonary congestion, progressing to pulmonary edema). Symptoms of a right sided problems include swelling of the legs and feet, followed by fluid in the abdomen and swelling of abdominal organs, particularly the liver, while risks are poorer blood flow through organs, particularly the liver, and failure of those organs.

Spring mechanism 327 is also suitable to provide a margin of reserve in the strength of contraction of the ventricles such that reduction of the systolic (contracting) pressure in that ventricle or ventricles would be expected to cause lesser problems than those relieved by reducing the diastolic (filling) pressure of that same ventricle.

Accordingly, spring mechanism 327 is useful in, but not limited to, such patients as recipients of a treatment, such as geometric remodeling of a ventricle with or without a specialized device as described herein or in U.S. Patent No. 5,702,343 (Acorn), U.S. Patent No. 6,085,754 (Acorn), U.S. Patent No. 5,961,550 (Myocor) or U.S. Patent No. 5,800,528

diuretic medicines. Furthermore, there is a lesser risk of symptomatic hypotension using the present invention than with the use of vasodilator medicines.

Fig. 32 illustrates one embodiment of the present invention. As shown in this figure, bundles 320 of spring wires 321 can be composed of spring wires 321 having an apical end 322 and linked by interlinking strands or tethers 324.

Fig. 33 illustrates halves of two bundles 320 shown inside and against the wall of a longitudinally sectioned left ventricle 331 (cut perpendicular to septum, viewing toward posterior wall) and having post tips 330.

Fig. 34 illustrates bundle 320 shown as seen from inside a longitudinally sectioned left ventricle (cut parallel to septum, viewing toward free wall 341), in relation to the apex 342 of the ventricle and base 340 of the ventricle.

Fig. 35 illustrates a top view of a transverse section of a heart in which two bundles 320 have been positioned against the free wall and septum, respectively, of the left ventricle. Fig. 35 illustrates bars or plates 350 of a ventricular remodeling device (as shown, for example, in Figs. 10A and 10B) which may be used in conjunction with spring mechanism 327 or another heart remodeling or surgical procedure such as those known to the art, including U.S. Patent No. 5,702,343 (Acorn), U.S. Patent No. 6,085,754 (Acorn), U.S. Patent No. 5,961,550 (Myocor), U.S. Patent No. 5,800,528 (Abiomed), or those described in McCarthy et al., "Early results with Partial Left Ventriculectomy", from the Departments of Thoracic and Cardiovascular Surgery, Cardiology and Transplant Center, Cleveland Clinic Foundation, Presented at 77th Annual Meeting of the American Association of Thoracic Surgeons, May 1997, 33 pages, all of which are hereby incorporated by reference.

Fig. 36 illustrates an enlarged view of the illustration in Fig. 35. As shown in Fig. 36, spring wires 321 can be covered with a polymer covering 360, such as a polymer such as knitted polyester, to facilitate tissue ingrowth. Fig. 36 illustrate cross-sections of such covered spring wires 321, respectively, before (left-side) and after (right-side) tissue ingrowth surrounding spring wires 321.

Fig. 37A illustrates an embodiment of an apical stabilization coupling 370, such as an apical cap including a mounting block that rests adjacent the apical portion of the heart and stabilizes fan-like array 323 adjacent or within an apicandial surface of the heart. In one embodiment, coupling 370 also fixes two or more bundles 320 of spring wires 321 together. Ventricle 331 shown in Fig. 37A has not been subjected to a geometric remodeling device.

surface of the ventricle, lying on the inner surface of the ventricle at or near its largest circumference, between that inner (endocardial) surface and the valve-support apparatus (chordae tendinae 431 and papillary muscle tips 432).

Fig. 45 illustrates a spring mechanism 327 including a U-shaped spring assembly 450 that can be placed in the ventricle via a transvascular catheter under fluoroscopic and/or echocardiographic control, with attention to orientation and length of the arms of the 'U' so as avoid deformation and immobilization of the atrioventricular (mitral or tricuspid) valve of the ventricle. The center segment of the 'U' shaped spring assembly 450 can be positioned against the inner surface of the apical portion of the ventricle, while the two arms can be positioned against the interventricular septum and the free wall.

Spring assemblies 410, 425, 430 or 450 can also include two or more of the assemblies pre-attached to each other at the ventricular end that are separated upon release following trans-apical introduction into the ventricular cavity. Spring assembly 410, 425, 430, or 450 can also allow for adjustment of spring mechanisms after placement to alter the outward force/deformation relationship. This may be, but is not limited to, local deformation of one or more spring segments by traction or torsion via a transvascular catheter.

Method for use

One embodiment of the method of use of devices according to the present invention includes the following steps. First, referring to Fig. 38, each bundle 320 of spring wires 321 is loaded into a separate removable, generally tubular, polymer sheath. A stab wound is the made in the apical end of the ventricle and dilated mechanically, with local pressure to control bleeding. The wire-containing sheath 380 is next introduced, with direction controlled by manual or instrument grasp of the solid post tip 330 of bundle 320. During guiding of the sheathed bundle 420 into the ventricle, position is maintained with the basal end against the inside wall, so as to be generally between the wall and chordae tendinae and/or valve leaflets. When fully advanced, a stylus is inserted in the outside end of sheath 380 and post tip 330 is maintained stationary while sheath 380 is withdrawn. This releases wires 321 of bundle 320 to 'fan-out' against the inside (endocardial) surface of the ventricular wall. In a preferred embodiment, placement will generally be either against the lateral wall, between the papillary muscles, or against the interventricular septum.

When the desired number of bundle(s) 320 have been placed, the ventricular apical stab wounds are controlled by purse-string sutures or other mechanical means, with post-tips 330

an initially placed tether or tethers as a guide and traction mechanism for main segment 10 positioning, as shown for example in Figs. 46A, 46B, 47A, 47B, 48A, 48A, 49A, and 49B.

Figs. 46A-53 illustrate several embodiments of devices and components of remodeling devices according to the present invention. Figs. 46A-50B each have a part "A" and a part "B," part "A" showing the heart in perspective view through various stages of clasp placement, and part B showing a longitudinal section at the same stage of the placement. This is a non-limiting example in which placement is about the left ventricle 460 and left atrium 461, and positioning of main segment 10 is on the anterolateral and posteromedial aspects of both these chambers. Figs. 46A-49B directly illustrate successive stages in a preferred method of placement, as well as the structure of the device.

Fig. 46A shows a tether 462, such as a cable, cord, band, chain, guide wire, and the like, that has been passed longitudinally around the heart. Tether 462 can be passed, for example, from the ventricular apex, along the posteromedial surface of the left ventricle, across the posterior atrioventricular junction, through the oblique sinus between the left and the right pulmonary veins (right side of the left veins, left side of the right veins), through an opening in the pericardial reflection separating the oblique and transverse sinuses, through the left part of the transverse sinus (anterior-superior to the "roof" of the left atrium, on either aspect of the atrial appendage, and posterior-inferior to the left and/or main pulmonary arteries), across the anterior atrioventricular junction, longitudinally across the anterolateral surface of the left ventricle, and returning to the apex.

Fig. 46A further shows that one end of this tether is attached to what is to become the atrial end of main segment 10. In another embodiment, the main segment 10 may have a channel (open or closed) from one end to the other which allows main segment 10 to be threaded onto a tether 462 after the placement described above.

A non-limiting example of a placement method includes placement of an endosurgical access port into the pericardial cavity and introduction of a flexible endoscope through that port as described below (see Fig. 162). The scope could be advanced (with or without supplemental carbon dioxide insufflation and/or positioning the patient with the left posterior chest upward for separation of planes) along the path described above or in the opposite direction, under visual control. Passage through the pericardial reflection may be achieved by either blunt puncture or nibbling via a flexible endoscopic forceps, such as a grasping or biopsy type as described below (see Figs. 163 and 164). Then, with the port withdrawn, the scope tip may re-exit the pericardial space along side its entry through the port incision. Next, one end of tether 462 (cable or other

to be placed in a minimally invasive operation, or a mini-incision operation, the openings of the anterior main segment 10 would continue into a sheath or carrier 481 (not shown) that is quite limp flexurally but stiff compressively. In either case, the separation distance of the anterior main segment 10 from the posterior main segment 10, at either end, may be adjusted at time of or subsequent to clasp placement, by advancing or withdrawing tether 462 into or out of the carrier sheath at its outer end.

Figs. 50A and 50B show an spacer or encasement 500 (e.g., formed of elastomeric material) placed at one or both ends between two main segments 10, surrounding tether 462 between the generally rigid main segments 10. During initial or subsequent tether length adjustment, spacer or encasement 500 can be compressed to varying degrees. The purpose of spacer or encasement 500 is to minimize potential tissue trauma by means of increasing the bearing area contacting the heart and other tissues. In addition, the separation of tether 462 from adjacent cardiac or noncardiac tissue or structures achieves a distribution of force and/or affects tissue response in order to reduce or eliminate risk of trauma to such tissue or structures. Spacer or encasement 500 does not substantially compromise either the freedom of length adjustment of tether 462 or the effect of such adjustment on the net force delivered to the ends of the main segments 10.

Fig. 51A shows a variation in which a tubular enclosing sheath 510, for example of either a solution-cast elastomer or one of the several materials successfully used for vascular grafts (knitted or woven polyester or expanded PTFE, for example) or other materials, is placed over tether 462, either at the time of tether insertion or subsequent to insertion of a heart remodeling clasp placement. Main segment 10, with or without spacer or encasement 500, are then inserted over tether 462 and within sheath 510. Sheath 510 may be of uniform diameter, but is preferentially of varied caliber to fit the varied component circumferences. In the case of caliber variation, it may be necessary for sheath 510 to be sufficiently elastic to allow passage of larger members.

Figs. 51B-51E illustrate additional embodiments of spacer or encasement 500 . Fig. 51b illustrates a tube 520 which is made from a porous material that is of stable circumferential dimension but freely compliant in length (within a desired predetermined operating range) to applied compressive or tensile force. An example criterion for free length compliance is, for example, that tube 520 alone will require less than 0.1N of either tensile or compressive force to either lengthen or shorten, respectively, the entire range of its operation.

whereby the external programmer may have the desired position or desired movement or desired force entered as a digital or analog signal.

Alternate Heart Remodeling Clasp

Fig. 54A shows one embodiment of an improved type of main segment 10 of a heart-remodeling clasp according to the present invention. It is similar to other main segments 10 in that it employs bimeridianal restraining segments 540 to reduce the wall-tension/chamber-pressure ratio. Bimeridianal restraining segments 540 include middle segment 541, and one or more shoulder sections 542 connected together and to middle segment 541 by hinges 543. In one embodiment, a traction cable 544 is anchored to one of end segments 542 at point 545 and passes through shoulder segments 542 and segment 540 via openings 546. In one embodiment, openings 546 are located opposite hinges 543 as shown in Fig. 54B.

As traction cable 544 is tensioned and pulled through openings 546 in the direction of arrow 547, shoulder segments 542 and bimeridianal restraining segments 540 are configured into the position shown in Fig. 54B where hinges 543 are closed. As the tension on traction cable 544 is released, the bimeridianal restraining segments 540 can return to the position shown in Fig. 54A. By tensioning or releasing the tension on traction cable 544, bimeridianal restraining segments 540 on the natural heart surface can be tensioned or released to the desired position to accommodate and/or assist systolic and diastolic function of the heart.

Figs. 54E and 54F show an embodiment of main segment 10 such as that shown in Figs. 54A and 54B except the relative width of each segment is larger.

Adjustable Stabilizing and/or Reconfiguration Segments

In one embodiment, as shown in Fig. 55, a heart remodeling clasp according to the present invention includes main segment 10 having compression segment 550, shoulder segment 551, and adjustable closure 552. Compression segment 550, for example, includes in one embodiment the features of segment plates 170 shown in the Figs. 17-31. Adjustable closure 552 can be any adjustable closure that will join main segments 10 and compression segments 550 at the top and bottom of the clasp. In one embodiment, adjustable closure 552 includes adjustable cable or strap 553, and releasable lock 554, as shown more specifically in Figs. 61 and 62.

The heart remodeling clasp according the present invention can also be used with adjustable stabilizer/reconfiguration segments 12 as shown in Figs. 56 and 58. Adjustable stabilizer/reconfiguration segment 12 are used to (a) stabilize the main segment 10 in position on the natural heart as shown, for example, in Figs. 63a and 63b and/or (b) to reconfigure one or

Fig. 67 shows the same embodiment as illustrated in Fig. 66, but from a side perspective using a stabilizer/reconfiguration segment 12 that is relatively wide compared to the size of the heart being treated. The orientation of main segments 10 can be placed on a heart without regard to the internal structure of the heart as required for devices internal to the heart. Accordingly, main segments 10 can be placed on the heart and achieve increased heart function (e.g., increased ejection fraction and decreased valvular regurgitation), as are not experienced with many internal devices.

All elements are configured to fit the particular portion of the heart on which they are to be placed. For example, as shown in Figs. 63a, 63b, 64a, and 64b, closure segments 552 can be configured to bridge the basal portions and apical portions of the natural heart.

Alternative Adjustable Stabilizing/Reconfiguration Segments Clasp with Pacing Leads

The present invention is also directed to an adjustable stabilizing/reconfiguration segment 12 for use with transceivers or pacing leads 694 capable of receiving and transmitting electrical signals, for example from a pacemaker. Referring to the figures, an exemplary natural heart 1 is shown in Figs. 68, 70 and 71.

A natural heart 1 has a lower portion comprising two chambers, namely a left ventricle 2 and a right ventricle 3, which function primarily to supply the main force that propels blood to and from the lungs, and the peripheral circulatory system, which propels blood through the remainder of the body. Natural heart 1 also includes an upper portion having two chambers, a left atrium 3 and a right atrium 4, which serve as an entryway to the left and right ventricles 2 and 3, respectively. As shown in Fig. 68, adjustable stabilizing/reconfiguring segment 12 includes one or more straps 680 (e.g., which may be suturable) which encircle the heart and are secured to any one or more of the main segments 10 described in this application, including a U shaped member segment as more fully described in U.S. Patent Application No. 08/035,710, incorporated herein by reference, with sutures.

Figs. 69A and 69B show alternate constructions of the main segment 10 and straps 680. In Fig. 69A, a cross-section is shown in which main segment 10 is encased in a suturable material encasement 690 such as a porous or non-porous material such as polyester mesh, woven polyester, silicone rubber, polyester fabric or reinforced silicone. Encasement 690 about main segment 10 provides a means for attaching straps 680 to main segment 10, which itself may be formed of material that would accept a suture. In Fig. 69B, main segment 10 is formed such that its exterior surface includes encasement 690, shown held in between two projections 691 in main

and electrical devices, electrical signals) as desired such that pacing or other manipulation or diagnosis of the heart may be readily accomplished.

In some cases, the stabilizer/reconfiguration segment may be sized to be slightly shorter than the exterior heart wall which it traverses so that it exerts a continual inward pressure on the wall and thus serves to reconfigure the heart in that location. In other embodiments, the stabilizer/reconfiguration segment is sized to exert little or no inward force on the heart wall and thus serves only as a stabilizer element.

Catheter Based System to Reduce Myocardial Wall Tension

The present invention is also directed to a method for placing restructuring or other devices into one or more chambers of the heart. In one embodiment, the method according to the present invention includes a catheter based system that may be used to place a system such as that shown in U.S. Patent Application No. 08/035,710 or U.S. Patent No. 5,961,440, both of which are hereby incorporated by reference.

In the present method, as shown in Figs. 73A-75B, via an artery leading to the ventricle, a catheter 730 is positioned within the left ventricle 2 in a non-invasive or minimally invasive procedure. A reversibly collapsible anchor 731 in the form of a clamshell or umbrella in its collapsed form is pushed outwardly through the left wall of left ventricular 2. This insertion of a reversibly collapsible anchor 731 through the wall may be aided with intravascular ultrasound. Once through the wall, anchor 731 opens to provide a nail or rivet-like planar surface that is then pulled back against the external surface of the wall. The same deployment of a second anchor 731 occurs on another portion of the wall of the left ventricle 2, for example on the wall of left ventricle 2 opposing the location of first anchor 731. Wires, cables or cords 732 attached to the anchors 731 are then connected and tightened, thereby decreasing this left ventricular dimension, and exerting a continual inward pull on the chamber walls, indenting the walls and reconfiguring the chamber. In one embodiment, a single wire, cable or cord 732 is used.

Fig. 74A shows anchor 731 open against the exterior wall of the left ventricle 2 after the two cords 732 have been placed. Fig. 74B shows the final cord 732 after joining and tightening of the two cords 732 originally placed. Figs. 75A and 75B show clamshell anchoring mechanisms which work in the same manner as the umbrella embodiment described above. The umbrella-like anchor may also include a head which when elongated is an elongated planar configuration rather than round so that pressure applied against the exterior surface of the heart creates an elongated indentation in the chamber.

echocardiographic, or other assessment.

Stabilization protrusions 174 are thought to work because initially the relatively tough epicardial layer of natural heart surface 1 is deformed at the site of pressure by stabilization protrusions 174 in a tent-like fashion downward into the natural heart surface, as shown in Fig. 76B. The muscle fibers and blood vessels 761 are free to move for short distances and will be displaced to one or the other side without damage. The 'tented' epicardium, so viscoelastically deformed, acts to counter potentially displacing tangential forces and thus to stabilize in position. Referring to stabilization protrusion 174, pressure on the very small surface area at the tip of stabilization protrusion 174 is quite high, approximately 1 to 5 megaPascals (7,500 to 37,500 mmHg). This pressure causes very localized tissue death or necrosis followed by loss of mechanical integrity. The epicardium will then separate, and the margins of the hole created in the epicardium surround the sides of the stabilization protrusion 174 toward the bar as shown in Fig. 76c. At this time, the muscle fibers and blood vessels 761 continue to be displaced to the sides of stabilization protrusion 174. Position stabilization for stabilization protrusion 174, and thus of the main segment 10 or stabilization/reconfiguration segment 12, is maintained.

There is a tendency for devices such as heart remodeling clasps including main segments 10 and/or stabilizer/reconfiguration segment 12, according to the present invention which are applied to the surface of the heart to become displaced tangentially due to the motion of the heart. This has particularly been observed, for example, in the acute experimental trials of clasps according to the present invention, in the absence of such local stabilization means.

The likelihood is that a broad-based area of fixation of an epicardial-contacting device would 'splint' or immobilize the layers of myocardium immediately subjacent to the device, such that part of the muscle mass could not effectively contribute to heart function. This could occur with stabilization protrusion 174 if placed along the width of main segment 10 as shown in Figs. 79C and 79D. Accordingly, in one embodiment stabilization protrusions 174 are confined to a narrow longitudinal centerline of a device such as main segment 10 of a heart remodeling clasp according the present invention, as shown in Fig. 79a. In Fig. 79a, only the first of multiple stabilization protrusions 174 are shown on main segment 10 in a top view in cross-section of main segment 10. In such devices, stabilization protrusions 174 may be an improvement over or used in addition to local fixation means such as adhesives and those methods and devices that promote scar tissue.

Stabilization protrusions 174 are different from sutures in that the protrusions do not require complex manual or instrumental manipulation to place. It is different from tacks or spikes

biocompatible polymer), a rigid or semi-rigid partially or fully absorbable tip 801, and a non-absorbable porous component 770 (e.g., a flexible or rigid mesh, wire or net). As shown in Figs. 81A and 81B, head 800 is attached to main segment 10 by any mechanical or chemical means. Then, stabilization protrusion 174, by delayed penetration as discussed above with respect to Figs.76A-76C, penetrates natural heart surface 1 by delayed penetration (the end result of which is shown in Fig. 81B), after which partially or fully absorbable tip 801 is absorbed as shown in Fig. 82A. The healing process of the myocardium which has been damaged by fiber separation causes collagen fibers to penetrate interstices in the porous component 770 as shown in Fig. 82B.

The composition of the stabilization protrusion 174 is selected and/or treated such that it will provide tangential stability of stabilization protrusion 174, and thus of main segment 10, on natural heart 1 until it is fully absorbed i.e., the stabilizing effectiveness of the rigid component continues until it is fully absorbed. The materials for fully or partially absorbable protrusion 174, or portions thereof, will ordinarily be selected to be partially or fully absorbable over a predetermined period of time.

Another embodiment of stabilization protrusion 174, as shown in Figs. 78a and 78b, according to the present invention is a spring-loaded, length-extending protrusion or peg. According to this embodiment, stabilization protrusions 174 have first and second sections 781 and 782, separated by a releasable holding mechanism 783 such as a wire or similar element, and a spring, elastic or tensioned band or wire 784, or similar element.

Stabilization protrusions 174 are initially engaged with natural heart surface 1 as discussed above up to the length of second section 782. After this initial penetration depth has been achieved, the penetration depth may be increased immediately or after a period of time by removing releasable holding mechanism 783 and allowing band or wire 784 to push stabilization protrusions 174 into natural heart surface 1 to an optimal depth.

This embodiment provides an initial limited penetration in the natural heart surface by stabilization protrusions 174 controlled by releasable holding mechanism 783, which opposes the extending force of band or wire 784. In one embodiment, band or wire 784 is formed of a silicone rubber strip. After main segment 10 is positioned on natural heart surface 1, releasable holding mechanism 783 is released, and the elastic or tension force of band or wire 784 causes stabilization means to penetrate natural heart surface to an optimal predetermined depth. Resistance of muscle fibers to displacement may or may not cause a detectable delay in full penetration.

Referring to Figs. 86A, 86B, 86C, 86D, 86E and 86Ff, first segment 850 (for example, basal segment for placement near basal portion of heart) is inserted into the tube using flexible push rod 865. Next, second segment 851 (for example, an anterior segment) is inserted into flexible sheath 830. Second segment 851 is then click-locked onto first segment 850. Next, third segment 852 (for example, a posterior segment) is inserted into flexible sheath 830 and is then click-locked onto the fist segment 850. Fourth segment 853 (for example, for placement near apical portion of the heart) is then inserted into its own flexible sheath 864 and is snapped into place with second and third segments 851 and 852 as shown in Figs. 86E, 86G, and 86H such that flexible sheath 864 on fourth segment 853 meets and seals with the flexible sheath 830 on second and third segments 851 and 852.

Another aspect of the present invention relates to apparatus and methods for altering the length or curvature of main segment 10. Fig. 87 shows a portion of a segment including a pull-cord version of a chain of hinged block forming, for example, a main segment 10 according to the present invention. As shown in Fig. 87, a series of blocks 870 having pivot pins 871 on one side, tapered edges 878 forming gaps 872 (see Fig. 89) on the opposite side, and a cable, cord or wire 873 attached to one of blocks 874 at one end of main segment 10. When the cable, cord or wire 873 is pulled, the side of the assembly on which blocks 870 have gaps is tightened and individual blocks 870 pivot around pins 871, with gaps 872 closing and blocks 870 coming into contact, thereby shortening that margin and bending the whole segment. Although only four blocks are shown in figure 87, any number of many more or less blocks can be used to form the desired length as shown in Fig. 89. As shown in Fig. 87, one of end blocks 874 is a cable-entry block, which is fixed to cable or cord or wire 873. When cable, cord or wire 873 is moved relative to the blocks 870, the other of end blocks 874 containing an end of cable, cord or wire 873 moves relative to the first end block 874 and main segment 10 bends. In one embodiment, one end of cable, cord or wire 873 is threaded into one of end blocks 874, and as a user winds or unwinds cable, cord or wire 873 into one of end blocks 874, one end of main segment 10 moves relative to the other end of main segment 10 and the segment bends. Although described with respect to main segment 10, the structure shown in Fig. 97 can be used for any of segments 850, 851, 852, or 853. Fig. 88 shows one example of two blocks 870 and one pin 871. Holes 877 receive cable, cord or wire 873.

In one embodiment, shown in Fig. 89, main segment 10 has a flexible outer sheath 890 which, for example is corrugated or smooth mesh, as in Figs. 51B, 51C, 51D, 51E, 69A, 69B, and 83.

overall segment. In this embodiment, a cable, cord or wire 931 is run throughout telescoping segments 930. At each end of main segment 10 are ends 932 which for example in this embodiment, have the male and female ball and socket joints as described above for adjoining several segments to each other. Optionally, a sheath 933 also surrounds the telescoping segments 930. Fig. 93B shows the effect of shortening main segment 10, for example by pulling the cable or wire or cord 931.

As described above, various mechanical means may be utilized to shorten cable, cord, or wire 931, such as simply pulling it, or using a threaded torsion end which moves in and out of end 932 as the cable, cord, or wire 931 is rotated. Moreover, any appropriate hydraulic or mechanical means may be used to shorten the overall length of the main segment by taking advantage of the series of telescoping segments 930.

Figs. 94 and 95 also show the use of a hydraulic system to change the length of a segment according to the present invention comprised of a series of telescoping segments 930. As shown in Fig. 94, as a fluid is pumped into the hollow segments 930, the pressure increases and segments 930 separate, increasing the overall length of main segment 10. Fig. 95 shows a similar embodiment but where the telescoping segments are of a slightly smaller width relative to their length.

Fig. 96 shows another embodiment useful for adjusting the length a segment according to the present invention. In this case, telescoping tubular segments 960 are placed over a cable 961. Cable 961 is also fixedly attached to a threaded segments 962 and 963 on each end of main segment 10. Each threaded segment 962 and 963 is disposed within an appropriate thread accepting housing 964 and 965 at each end of main segment 10. Threaded segments 962 and 963 are disposed opposite each other so that rotation of the cable 961 in one direction causes compression between the two threaded ends. In this embodiment, optionally a sheath 966 surrounds telescoping segments 960.

Cable 961 can be rotated mechanically or electromechanically from a local or remote source. In the case of electromechanical rotation of cable 961, an appropriately geared motor may be used to rotate or torque cable 961 or it can be interposed along the cable itself. In the embodiment is shown in Fig. 97, cable 972 is rotated via motor 970 which is powered and controlled by wires 971. Motor 970 may be within or outside the patient.

In another embodiment, hydraulics similar to those was discussed above, may be used to supply fluid pressure to telescope main segment 10. Fig. 98 shows an embodiment where a

as those shown in Figs. 101A, 101B, 101C, 101D, 101E, 102, 103, 104, and 105A-114B. The coupling is positioned between the superficial mechanism and the mechanism internal to the clasp. The clasp internal mechanism is located within or upon one or more components of main segment 10 which responds to superficial mechanism adjustment by effecting a change in the relative position of the heart-contacting surfaces of two or more main segments 10 related to one another, of some portion or portions of main segment 10, and/or of the adjustable stabilizer/reconfiguration segments 12.

An embodiment of an adjustment assembly of the invention is illustrated in Figs. 101A, 101B, 101C, 101D and 101E. In this embodiment, rotation of a cable 1010 effects a change in the position of main segment 10 and/or adjustable stabilizer/reconfiguration segment 12. As shown in Fig. 101A, cable 1010, such as a cable, cord, wire, is located within a casing 1012 and is attached to main segment 10 and/or adjustable stabilizer/reconfiguration segment 12 (not illustrated). A tip 1013 (shown in Fig. 101B) of cable 1010 is covered by cap 1012 that is removably connected to the casing 1011 covering cable 1010. Cap 1012 can be removably connected to the casing 1011 using conventional means, such as a pressure fit, suturing, and the like.

As shown in Figs. 101B and 101C, cap 1012 can be disconnected from casing 1011 such that a tip 1013 of cable 1010 is exposed. In the embodiment shown in Fig. 101B, a pressure clip 1015 is removed from cap 1012. Tip 1013 can then be rotated using an instrument 1014, such as screwdriver or allen wrench, to turn cable 1010. Rotation of cable 1010 effects a change in the relative position of the heart-contacting surfaces of two or more main segment 10 bars, of some portions of main segments 10, and/or of the adjustable stabilizer/reconfiguration segment 12. Following adjustment of main segment 10 and/or adjustable stabilizer/reconfiguration segments 12, the cap 1012 can be reconnected to the casing, as shown in Fig. 101d. Fig. 101e illustrates an exemplary screw mechanism 1016 for rotating cable 1010 within casing 1011.

Fig. 102 illustrates another embodiment of an adjustment assembly of the present invention. The adjustment assembly illustrated in Fig. 102 includes a direct push-pull-driven linearly moving cable 1020 surrounded by a casing 1011. Cable 1020 illustrated in Fig. 102 can include a removable cap, such as the removable cap 1012 illustrated in Figs. 101A, 101B, 101C, 101D, and 101E. A push or pull movement of cable 1020 within casing 1011 causes a change in the relative position of the heart-contacting surfaces of two or more main segments 10, of some portion or portions of main segments 10, and/or of adjustable stabilizer/reconfiguration segments 12. The position of cable 1020 can be locked after adjustment by a set-screw, a knot, and the like

movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Fig. 108 illustrates a screw-operated pusher 1080 driven by a torque-cable 1081 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Figs. 109A and 109B illustrate a screw-operated lever 1090 operated by a pull cord 1091 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061.

Fig. 110A and 110B illustrate a screw-operated lever 1100 operated by a torque-cable 1101 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. When cable 1101 is rotated, threaded segments 1101 and 1103 cause levers 1100 to come toward each other which results in the separation of surfaces 1060 and 1061 as shown in Fig. 110b.

Figs. 111A and 111B illustrate a hydraulic bellows 1111 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Figs. 112A and 112B illustrate a hydraulic piston 1121 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. In another embodiments inner surface 1060 is moved relative to outer surface 1061via a direct hydraulic space 1122 between inner and outer surfaces 1060 and 1061, respectively is illustrated in Figs. 113A and 113B. Figs. 114A and 114B illustrate screw-approximating shims 1140 for movement of the inner (heart-contacting) surface 1060 relative to outer surface 1061. Here, shims 1140 are moved toward each other as the cable 1141 is rotated. This causes the separation of the inner (heart-contacting) surface 1060 relative to outer surface 1061.

As discussed above relative to Figs. 37A and 37B, the present invention can also include an apical cap (or bowl-shaped device) that fits over the outer (epicardial) surface of the apical part of the left ventricle for stabilizing devices adjacent heart 1. Such an apical cap may or may not extend onto the apical portion of the right ventricle. This aspect was discussed briefly above in regard to Figs. 37a and 37b which illustrate an embodiment of an apical coupling 370, such as a mounting block or cap, that fixes two or more reconfiguring bundles 320 of spring wires 321 together. Such an apical cap can also be used to stabilizing main segment 10 on the heart.

As shown in Fig. 115, apical cap 1150 (e.g., coupling 370 described with respect to Figs. 37A and 37B) has a shape and stiffness, particularly in the radial direction, which will not allow it to move substantially in any direction perpendicular to the long axis of the left ventricle. It provides, therefore, a stable anchoring member to prevent motion of a device on or in the heart surface, such as main segment 10 or bundle 320 of springs 321.

As shown in Figs. 115 and 116, apical cap 1150 is designed to fit adjacent the apical part

Fig. 125 illustrates apical cap 1190 with circumferential purse strings 1250 entered around one or more portions of apical cap 1180, that may be used to adjust the shape and size of apical cap 1190 as described with respect to Fig. 123. Four such purse strings are shown in Fig. 125, but any number may be used. As discussed with respect to Figs. 69A-72 above, apical cap 1190 may include pacing leads or transceiver elements such as those on main segment 10 or stabilizer/reconfiguration segment 12.

Fig. 126 shows an embodiment for releasably securing cable 481 as shown in Fig. 52, to main segment 10 having a center modular portion 1260, using a remote cable-clamping mechanism. Such a configuration is used to facilitate the general scheme of tether, cable, cord or wire-mounted clasp members by providing ease of placement and remote adjustability, while eliminating the reduction of positional stability inherent in long tethers, cables, cords, or wires disposed within sheaths. It should be noted that when the word "cable" is used, it is intended to be synonymous with the words, tether, cable, cord, wire, chain, strap, or other similar restraining device.

The general principle of this aspect of the invention is that of a cable-car clamp or a detachable ski-lift clamp. The resting position of the spring-activated clamp or brake is closed, so as to prevent cable movement. An active maneuver is required to effect spring release. Thus, the failure mode would presumably be loss of adjustability, as opposed to loss of cable stability.

In one embodiment, the mechanism is a fixation device located on a main segment 10, that can be released and adjusted remotely by an adjustment cable or other means. The clamp-releasing cable itself is different from the cable or tether that was described above with respect to Fig. 52 with regard to the clasp placement system and adjustment. When the cable clamp is released, transiently, by means of this alternate type of cable, the primary (clasp-supporting) cable may be adjusted in length. When the clamp is re-tightened, the primary cable length is again fixed.

In an embodiment shown in Fig. 126, a main segment 10 is shown with an apical cable 1261 partially exposed as it passes through apical segment 1262 of the spine of main segment 10. Sheath 1263 covers an atrial cable 1265 (not shown, but identical to apical cable 1261) and sheath 1264 covers apical cable 1261. It is the cables within sheaths 1263 and 1264 which can control the compression of main segment 10, as described in more detail below. Cables 1261 and 1265 may be the ends of one cable or two or more cables linked together, for example linked by one or more portions of main elements 10.

Fig. 138 shows an enlarged view of a portion of locking mechanism 1372 showing purse string attachment points 1380, as discussed above with respect to a stabilizer/reconfiguration segment 12 in Figs. 7, 8, 10A and 10B.

Locking mechanism 1372 shown in Fig. 139 includes cables 1261 and 1265 which pass from umbilical-like connection 1371 into locking mechanism 1372, control cable 1390, spring 1393, and locking wedge 1392. In one embodiment, length of cables 1261 and 1265 is controlled through a ratcheted spool mechanism contained in a control box 1370.

The proximal end of the control cable 1390 is fixed to the control box and the distal end is fixed to the spring loaded locking wedge 1392. Locking mechanism 1372 is composed of locking wedge 1392 and spring 1393, as well as a wedging surface 1394, which is integral with the device frame. A wedging surface 1394 of locking wedge 1392 creates a pinch point for cables 1261 and 1265 between the wedging surface 1394 and a wedge 1400 itself. Wedge 1400 is spring loaded to insure the system will be locked when in the default position. The user can control the locking system through control cable 1390, which passes through umbilical sheath 1371. When the locking system is in the unlocked position, the cables 1261 and 1265 are be tightened or loosened thereby decreasing or increasing the space between two main segments 10. The control box controls cable length and cable tension.

In use, as control cable 1390 is rotated, spring 1393 is compressed and releases pressure on locking wedge 1392 which allows cables 1261 and 1265 to be tightened or loosened. To again secure cables 1261 and 1265 to wedging surface 1394, control cable 1390 is rotated in a opposite direction to decompress spring 1393.

Figs. 141 and 142 show an additional embodiment of the pad as described with respect to Fig. 55. Pad 550 has a hardness of 40 to 60 Shore A, and preferably is formed from a polyurethane rubber or implantable grade silicone. The longitudinal radius of curvature of pad 1430 as shown in Fig. 142 is designed to insure enough curvature to effect the desired shape change of a heart or chamber thereof. For example, the longitudinal radius of curvature of main segment 10 can range from convex to concave toward the heart and can be in the range of minus 120 mm to positive 120 mm.

The radius of curvature of the lateral edges of main segment 10 or plates 170 (as described above) have a radius of curvature in the range of 0.2 mm to 10 mm so the edges do not impact negatively on the heart surface.

partially behind the right atrial appendage.

Fig. 146 shows a top view partial cross-section of the base of the heart with both atria and both aorta and pulmonic artery transected at their bases. Fig. 146 shows collar 1440 connected to tether 1442 which is in turn connected to main segment 10. Fig. 146 also provides a view of right ventricle 1460, mitral valve area 1461, tricuspid valve area 1462, aortic root 1463, and pulmonic root 1464.

Fig. 147 shows a heart with a first band 1470 passing around the right atrioventricular junction, and second band 1471 passing about the left atrioventricular junction, where first and second bands may be stabilizer/reconfiguration segment 12 as described for example in Fig. 5-8, or 68. Fig. 148 shows a top partial reduced cross-sectional view of the base of the view showing Fig. 147.

Figs. 149A and 149B show bands 1470 and 1471, respectively, off the heart. In one embodiment, section 1490 of band 1470 is the narrow region intended to pass through the transverse sinus behind the aorta. In one embodiment, bands 1470 and 1471 are made generally of a low-durometer medical polymer, with a cross-sectional contour molded to the general shape evident from the cut ends in Fig. 149b, as well as the cross section of stabilizer/reconfiguration segment 12 shown in Figs. 6 and 150. The material used to form the device according to the present invention, particularly the major components thereof, is similar to a closed-cell foam such as neoprene, in terms of transverse stiffness and longitudinal flexibility. A fabric reinforcement may also be used or included in this element of the device. Also, bands 1470 and 1471 may include transverse stays and/or drawstrings for shortening adjustment, such as that which is shown in Figs. 8, 10, 11A 11B.

Section 1490, which is intended to pass through the transverse pericardial sinus, is more nearly circular in cross section to match the anatomy in that location and to present a soft, blunt surface to underlie the right coronary artery. The overall width of band 1470 at their mid portion is generally about 10-30 mm, with a thickness of about 3 to 4 mm. Section 1490, in the area it passes through the coronary sinus is generally oval in cross section with a major axis of generally 8 to 10 mm and a minor axis of about 5 to 6 mm.

Band 1471 is shown in more detail in Fig. 149a. This band is generally similar the band 1470 described above, except this band has a relatively consistent cross-section rather than a variable cross-sectional section 1490 present on band 1470.

Aortic collar 1440 is a cylindrical cuff collar of, for example either fabric, low-durometer

This aspect includes a method of locally fixing portions of a sheath or jacket to the epicardium, including fine sutures, adhesives, and mechanical fixation devices such as staples and clips, or combinations thereof.

Fig. 151 is a perspective view of a portion of a main segment 10 which is clad with an fabric sheath 1510 in accordance with the present embodiment. For this embodiment, stabilization protrusions 174 (such as shown in Figs. 77a, 77b, and 77c) extend through openings in the sheath 1510.

Fig. 152 is a perspective view of the device shown in Fig. 151, but from the outer (away from the heart) surface. Sheath 1510 is locally adhered (via form fitting or an adhesive or mechanical attachment) to the main segment 10 at discrete locations such as along parallel lines of attachment 1521. Segment 1520 is a backbone (e.g., a rigid rod) of main segment 10 that is to be attached to the heart in accordance with this embodiment, and pad 1522 is shown as covering segment 1520 to prevent segment 1520 from directly contacting the heart surface.

Fig. 153 is a cross section of the segment and sheath shown in Fig. 152. Stabilization protrusion 174 is shown in this view and is consistent with the disclosure above regarding delayed surface penetrating pegs shown in Figs. 76A-82B. Outer edges 1531 of sheath 1510 (at the pad margin) are fixable (e.g., by adhesive, sutures, staples, clips, rivets, etc.) to the epicardium. Pad 1522 can be attached at the region of sheath 1510 that crosses the outer part of pad 1522, or, preferably, include a seam or fold to present a more convenient region for suturing, adhering, or stapling of pad 1522 to the epicardium.

Fig. 154 shows a perspective view of the entire clasp according to one embodiment of the present application, including basal bridging section 1540 and apical bridging section 1541, both clad in a sheath 1510 consistent with the above disclosure, and two main segments 10. Sheath 1510 in this embodiment covers posterior main segment 10 and the bridging sections, basal section 1540 and apical section 1541. Sheath 1510 also covers anteroapical and anterobasal junctions 1542 and 1543, respectively, which are junctions between the basal section 1540 and apical section 1541 and main segments 10. Sheath 1510 can be used to cover one or more desired portions of main segment 10 and/or basal bridging section 1540 or apical bridging section 1541. Also shown are adjustment strings or cables 22 (as discussed for example with respect to Fig. 7) exiting from the anterior main segment 10 within sheaths 1544.

Fig. 155 shows the embodiment of Fig. 154 except that a dense sheath 1510, such as one made from polyester mesh of expandable PTFE (e.g., porous or non-porous), is shown. The

namely dilator body 1594 is formed from a soft elastomer reinforced with spiral wire and having a center channel 1597. Dilator body is approximately 30 to 40 cm in length, and has two ends a body connector end 1598 and free end 1599 (seen in Fig. 159). Outside threaded connector 1595 has the same length as the inside threaded connector 1596 described above in regard to dilator nose 1590.

The third component is a dilator clasp adapter 1610 and is shown in Fig. 161A-161D. Dilator clasp adapter 1610 has two ends, a dilator body connecting end 1611 and a clasp connecting end 1612 (such as for connecting to one end of main segment 10). Dilator body connecting end 1611 is circular in cross-section with a diameter the same as that of the body, and it is equipped with a threaded connector identical to that of dilator nose 1590. Clasp connecting end 1612 has a cross-section and dimensions similar to the clasp segment to which it is to be attached (shown in Fig. 167). In one embodiment, clasp connecting end 1612 is generally flattened, and wider in the direction tangential to the heart than in the direction normal to the heart surface. Clasp connecting end 1612 has a projection 1612 that is elliptical in cross-section and tapered over its length. Projection 1612 is intended to fit into a corresponding mating socket in the clasp segment to which it is to attach, so that the clasp segment will not rotate on its long axis after attachment. As shown in Figs. 161C and 161D which are taken along lines C-C' and D-D', respectively, in Fig. 161A, dilator clasp adaptor 1610 includes a channel 1614 for accommodating a guidewire (not shown).

A method of using several devices according to the present invention is shown in Figs. 162-170. Fig. 162 shows a schematic representation of a heart located in a chest cavity. Fig. 162 shows that a small incision has been made into the subcutaneous tissue of the upper abdomen wall at point 1624, just below the lower rib margin, near the xiphoid process (that is, the or xiphisternum or the lowest part of the sternum or 'breast bone'). Then, using blunt and sharp dissection, the junction of the abdominal wall muscles and diaphragm is exposed and opened. Next, the pericardial sac is opened. The tip of a sterile flexible fiberoptic endoscope 1620, such as a bronchoscope, is introduced into the pericardial cavity, and, with visualization through the scope 1625, advanced behind the left ventricle 1621 and then behind the posterior wall of the left atrium 1622. Note that although Fig. 162 shows an eyepiece 1625 for illustration, the endoscope will typically be equipped instead with a video camera and image shown on a monitor as the surgeon advances the endoscope, allowing sterility to be maintained. Other structure shown is sternum 1623.

Fig. 171 shows the clasp including two main segments 10 in place, portions labeled as in Figs. 169 and 170, with the tether 1651 (optionally in outer sheaths 1711) in tether channels (no shown) on or in the clasp and extending into the subcutaneous incision. At this point, tether channels and tether 1651 ends may be connected to any adjusting and locking mechanisms discussed above, that are designed for use with the clasp in accordance with the present invention.

Another aspect of the present invention relates to that which is disclosed above with regard to clasp placement or fixation. In this embodiment, areas of hook and pile type Velcro® fasteners or similar reusable and removable fasteners, in a biocompatible material, are fixed, directly or indirectly as parts of a patch that is to be attached to the epicardium. Mating areas of hook and pile type Velcro® fasteners are part of a composite sheath within which the to-be-mounted structure is clad.

The type of Velcro® fastener selected (in terms of distribution) is such that the desired degree for freedom of placement and readjustment is obtained. Corresponding Velcro® fastener strips placed on the heart and the device may be parallel or perpendicular to one another.

Regions of Velcro® fasteners can include more elastic, fabrics of near equal thickness and thickness-compliance are combined so that lateral elasticity of these flexible composite structures is maintained. This is employed in construction of both the epicardial layer (containing hook and pile type Velcro® and more elastic fabric) and the sheath that is place about the to-be-mounted structure or structures.

More specifically, securing one side of the Velcro® fastener to the epicardium is generally done by multiple discrete fixation points, whether superficial (epicardium) sutures, rivets, cements, or very superficial staples, so as not to preclude segmental shortening or relaxation of the subepicardial myocardial layers. Securing other side of the Velcro® fastener to the to-be-mounted clasp segments (e.g., main segments 10) is similarly kept localized, generally on a surface not in contact with the heart (outer surface), along a single line perpendicular to the direction of maximal wall contraction (circumferential)—i.e., the center line of a vertical structure—or both.

A pattern of patch construction using 4-5 mm wide vertical (relative to the heart) strips of hook and pile type Velcro® fastener alternating with 5-7 mm wide strips of far more elastic polymer knit or weave, joined by flat stitching, and a similar sheath material, including alternating 3-4 mm wide Velcro® fastener and 4-5 mm wide elastic polymer in the structure sheaths, are non-limiting examples of such a system.

What is claimed is:

1. A device for treating a diseased heart, said device comprising:

one or more members configured to surround a selected portion of the heart, including a first member configured to be positioned adjacent an exterior surface of one chamber of the heart and to selectively deform the chamber by pressing inwardly thereon, and

a second member coupled to said first member, and configured (a) to lie adjacent an external surface of the heart in a path forming an angle with said first member and (b) to stabilize said first member on the heart.

2. A device according to claim 1, wherein said second member is a segment configured to selectively deform a portion of the heart.

3. A device according to claim 1, wherein at least a portion of said second member is a segment configured to lie adjacent the valvular annulus of the heart.

4. A device according to claim 1, wherein at least a portion of said second member is configured to lie adjacent the papillary muscle of the heart.

5. A device according to claim 1, wherein at least a portion of said second member is configured to lie adjacent the left ventricle of the heart.

6. A device according to claim 1, wherein at least a portion of said second member is configured to lie adjacent the right ventricle of the heart.

7. A device according to claim 1, wherein said second member includes a porous segment.

8. A device according to claim 1, wherein said second member includes a lattice structure.

9. A device according to claim 1, wherein said second member includes a segment configured to have an adjustable length.

10. A device according to claim 1, wherein said second member is rigid.

11. A device according to claim 1, wherein said second member is semi-rigid.

12. A device according to claim 1, wherein said second member is flexible.

said facing material being configured to facilitate epithelial growth into said facing material.

25. A device according to claim 24, wherein said facing material is porous.

26. A device according to claim 24, wherein said facing material includes a protrusion.

27. A device according to claim 26, wherein said protrusion is a molded projection.

28. A device according to claim 24, wherein said facing material includes a sheath configured to surround a portion of said first member.

29. A device according to claim 28, wherein said sheath is porous.

30. A device according to claim 28, wherein said sheath is elastic.

31. A device according to claim 28, wherein said sheath is configured to be secured to an external surface of the heart.

32. A device for treating a diseased heart, said device comprising:

one or more members configured to surround a selected portion of the heart, including a first member configured to be positioned adjacent an exterior surface of one chamber of the heart and to selectively deform the chamber by pressing inwardly thereon, and

a second member coupled to said first member, and configured (a) to lie adjacent an external surface of the heart in a path with said first member and (b) to stabilize said first member on the heart.

33. A device according to claim 32, wherein said second member is configured to lie adjacent an apical portion of the heart and to accommodate a portion of said first member.

34. A device according to claim 33, wherein said second member is a conical.

35. A device according to claim 33, wherein said second member is configured to have an adjustable size.

36. A device according to claim 33, wherein said second member includes at least one protrusion configured to accommodate a portion of said first member.

said second member including one or more elements configured to penetrate an exterior surface of the heart.

47. A device according to claim 46, wherein said second member includes protrusions configured to penetrate only an outer part of the exterior surface of the heart wall.

48. A device according to claim 47, wherein said protrusions are configured to be retained within the heart wall.

49. A device according to claim 46, wherein said second member includes protrusions configured to penetrate through the exterior surface of the heart wall and to be retained on an inside surface of the heart wall.

50. A device for treating a diseased heart, said device comprising:

one or more members configured to surround the heart, including a first member configured to be positioned adjacent an exterior surface of one chamber of the heart and to selectively deform the chamber by pressing inwardly thereon, and

a second member configured to stabilize the first member of said device in a preselected position on the heart, said second member including one or more elements attached to said second member at spaced locations and configured to pass through the exterior surface of the heart.

51. A device according to claim 50, wherein said elements are sutures.

52. A device for treating a diseased heart, said device comprising:

a first member configured to contact a surface of a chamber of the heart and to continually bias a wall of the heart, and

a second member connected to said first member and configured to stabilize said first member in a preselected location in contact with the surface of the chamber.

53. A device according to claim 52,

further comprising a third member connected to said first member and configured to be positioned on an exterior surface of the chamber and to selectively deform the chamber.

54. A device according to claim 52, wherein said first member is a spring.

55. A device according to claim 54, wherein said spring is a helical spring.

56. A device according to claim 54, wherein said spring is a leaf spring.

attaching a first portion of the device to one end of the tether,

pulling a first portion of the device into approximate placement position with the tether,

attaching a second portion of the device to the second end of the tether,

sliding the second portion along the tether and placing the second portion of the device into approximate placement position abutting said first portion, and

connecting the two portions to one another.

71. A method according to claim 70, further comprising the step of passing the tether and a portion of the device through an opening in a pericardial reflection of the heart.

72. A method for placing on a diseased heart a device including a tether having two ends, said method comprising the steps:

passing a tether having two ends along a predetermined line of approximate placement on the heart of the device,

sliding a sheath over the tether,

attaching one end of the sheath and one end of the tether to a first portion of the device,

pulling the first portion of the device into approximate placement position on the heart,

disconnecting the sheath and sliding the sheath off the tether,

attaching a second portion of the device to the tether,

sliding the second portion along the tether and placing the second portion of the device into approximate placement position, and

connecting the two portions to one another.

73. A method according to claim 72, further comprising the step of passing the tether, sheath and a portion of the device through an opening in a pericardial reflection of the heart.

74. A method for placing a device in a diseased heart, the device including a first automatically reversibly collapsible anchor and a first tether attached thereto, and a second

anchor is expanded to a relatively larger diameter including a relatively planar surface, and the anchor member is attachable to a tension member extending away therefrom, said method comprising the steps:

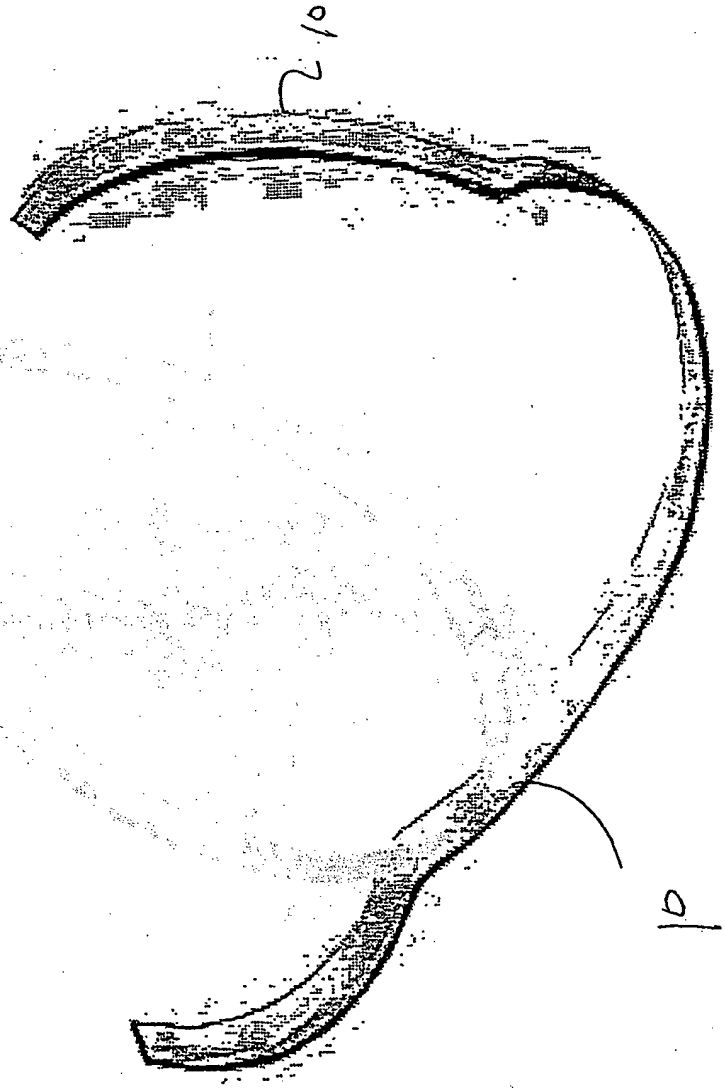
endoluminally introducing a first anchor into an interior of the chamber in the compressed configuration and causing the first anchor to pass through a wall of the chamber to the exterior thereof,

causing the first anchor to expand to its expanded configuration with the planar surface resting against an exterior surface of the chamber wall,

endoluminally introducing a second anchor into an interior of the chamber in a compressed configuration and causing the second anchor to pass through a wall of the chamber to the exterior thereof,

causing the second anchor to expand to its expanded configuration with the planar surface resting against an exterior surface of the chamber wall, and

connecting the first and second anchors to a tension member.



(Fig. 2A)

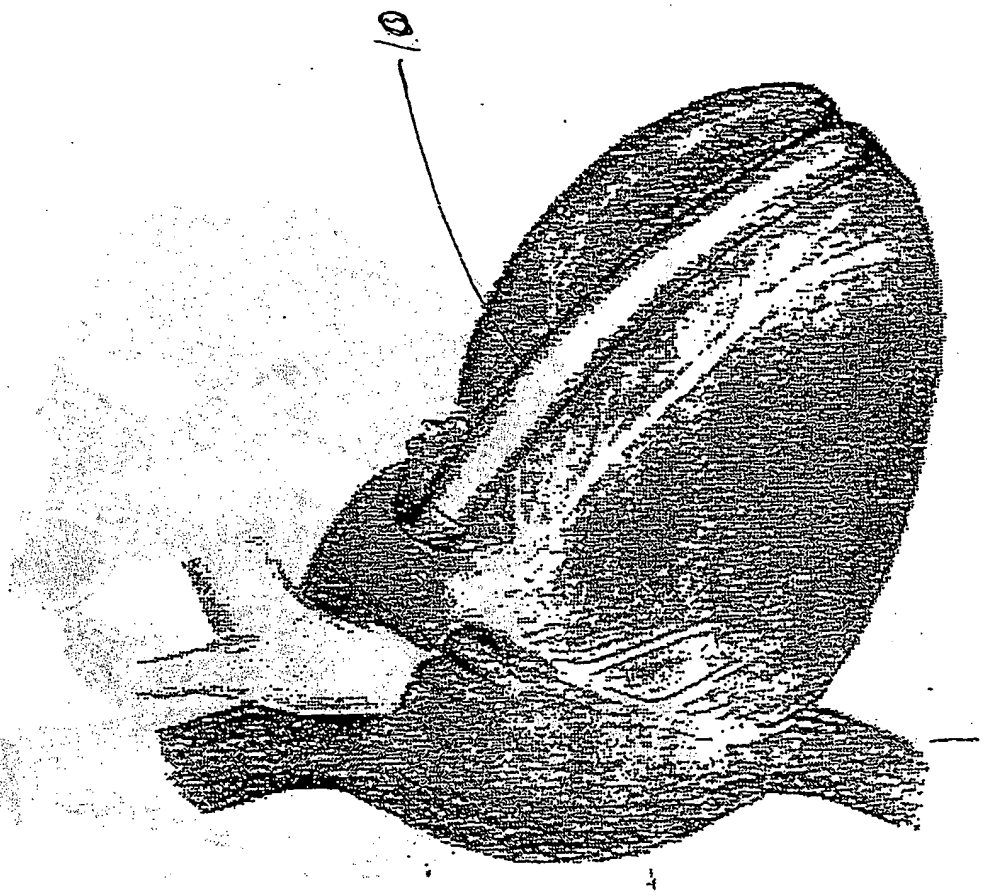


Fig 3

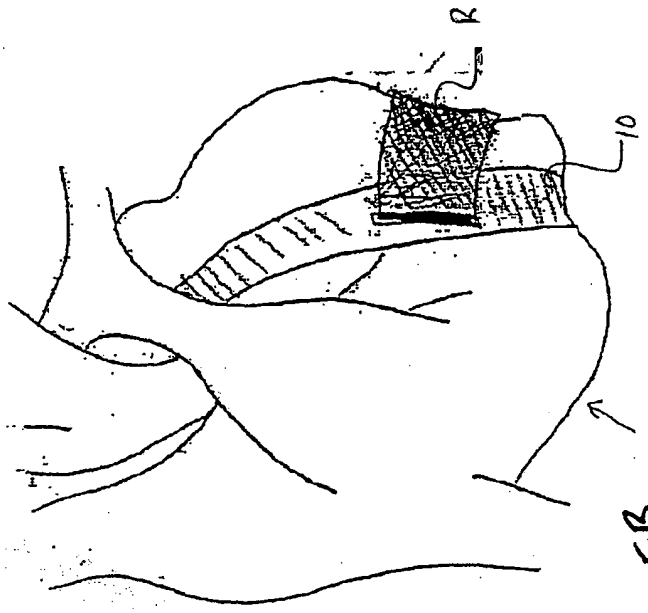


Fig. 5B

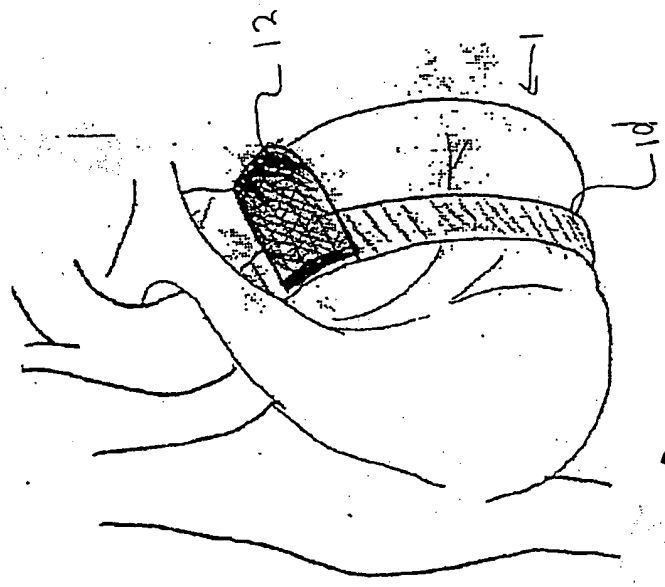


Fig. 5A

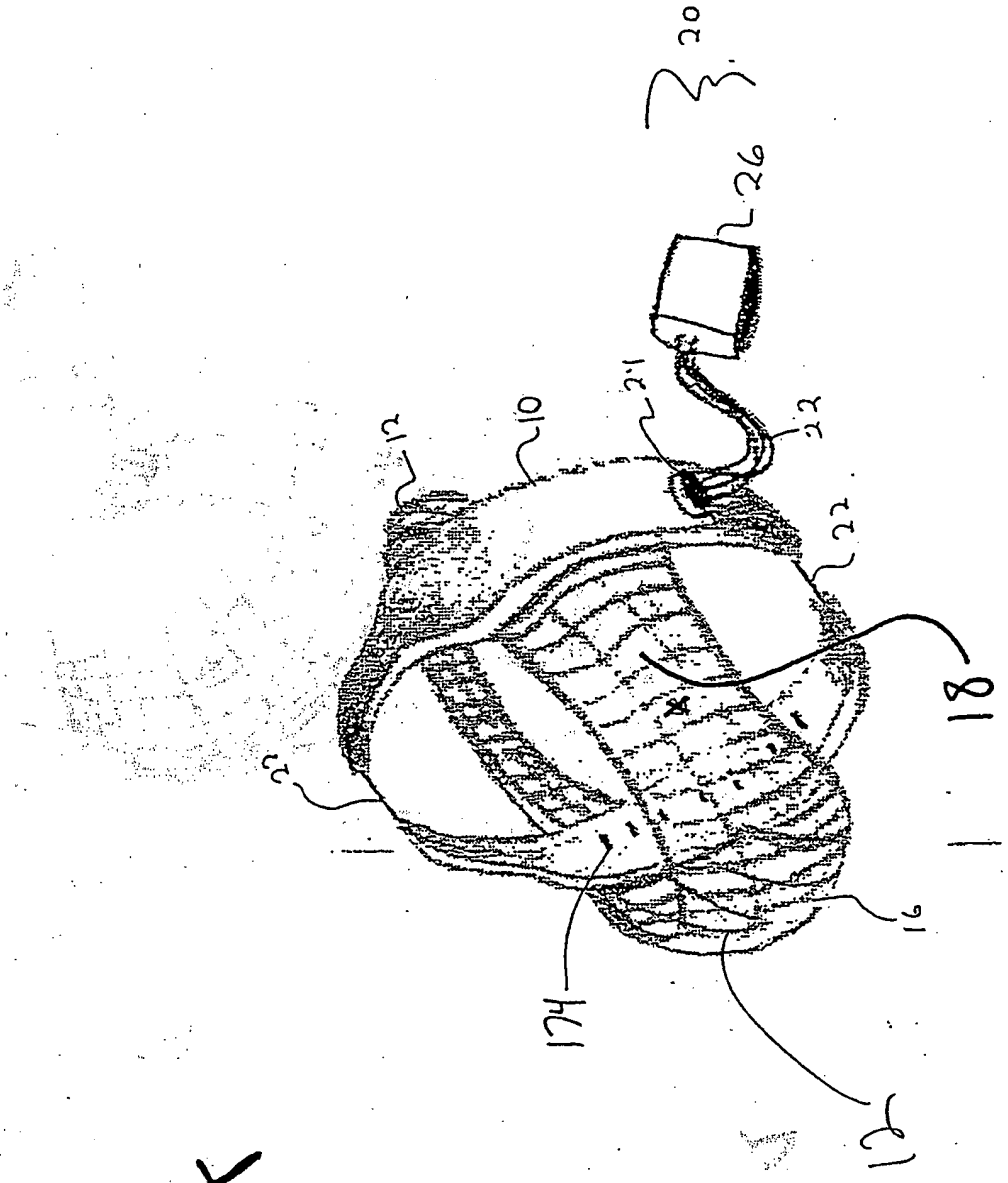


Fig. 7

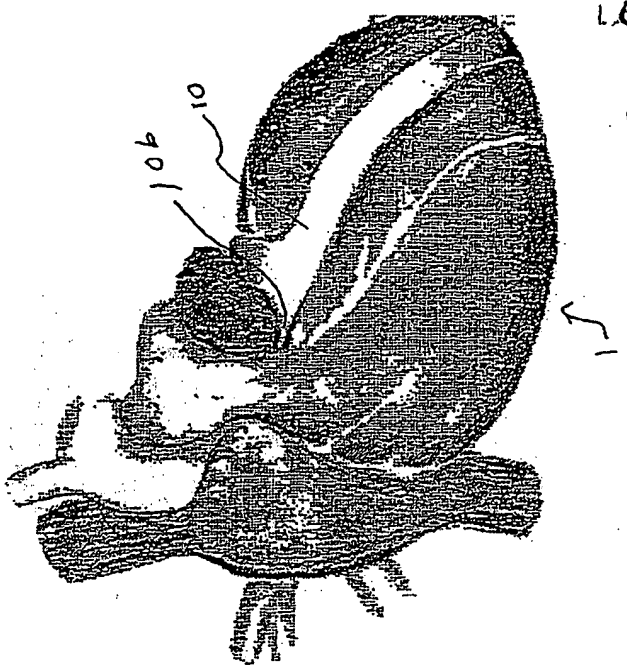


Fig 9B

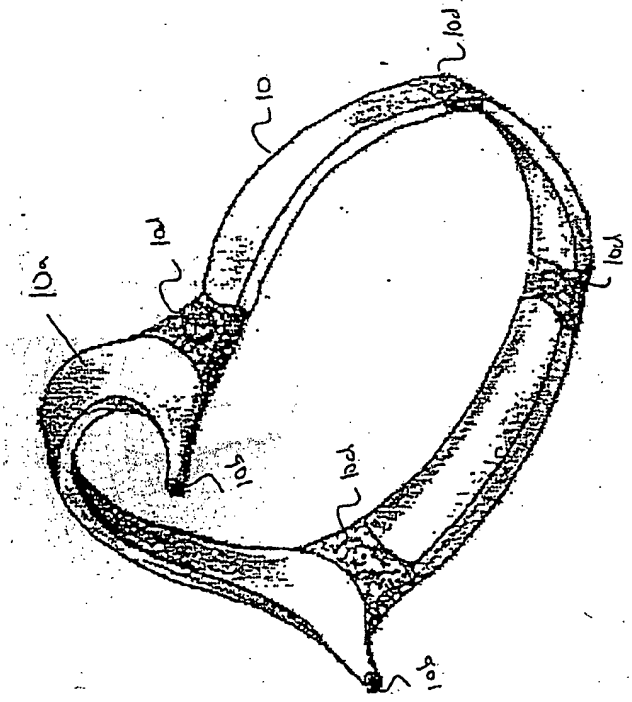


Fig. 9A

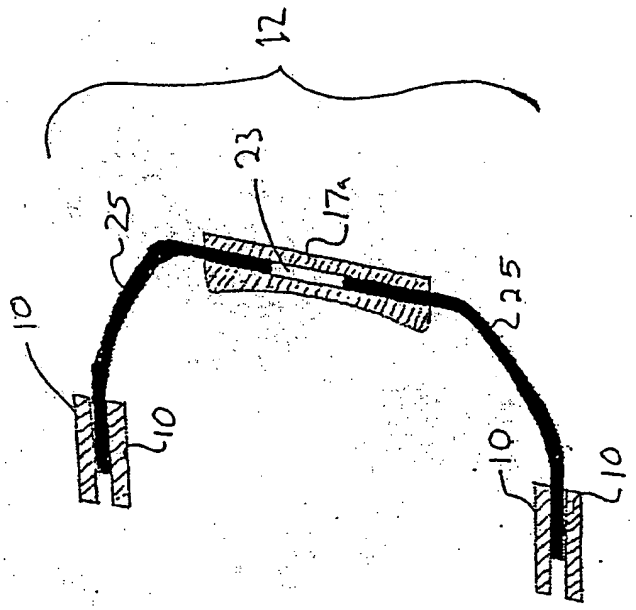


Fig 11B

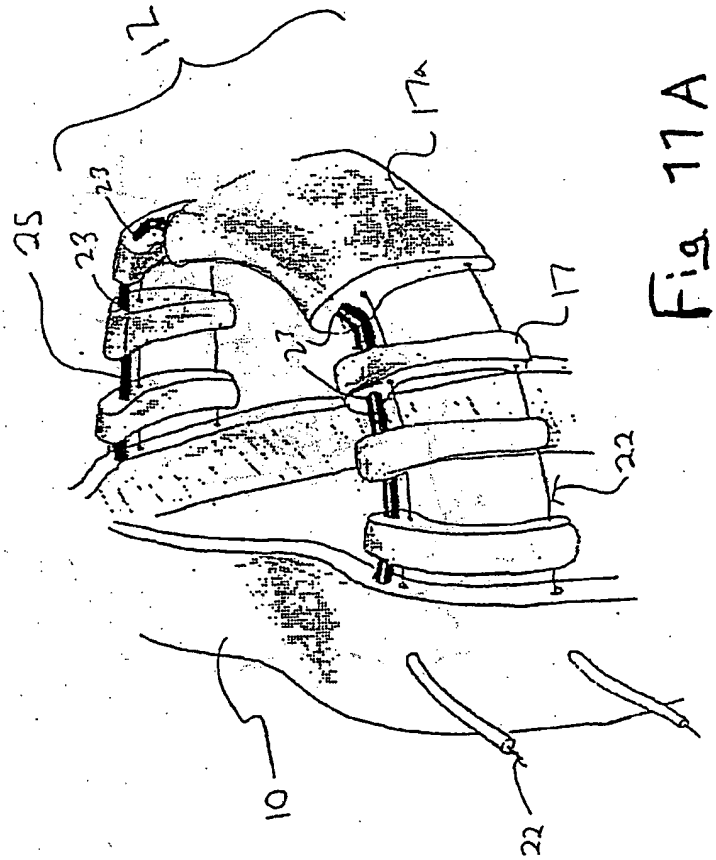


Fig 11A

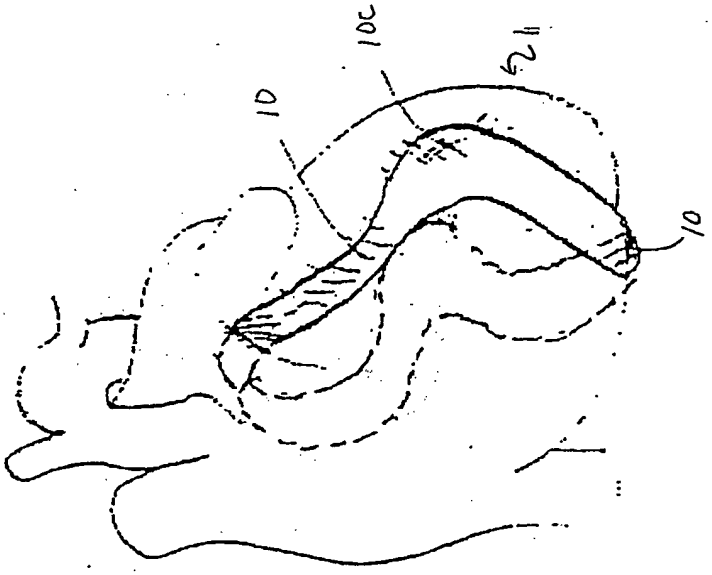


Fig. 13B

Fig. 13

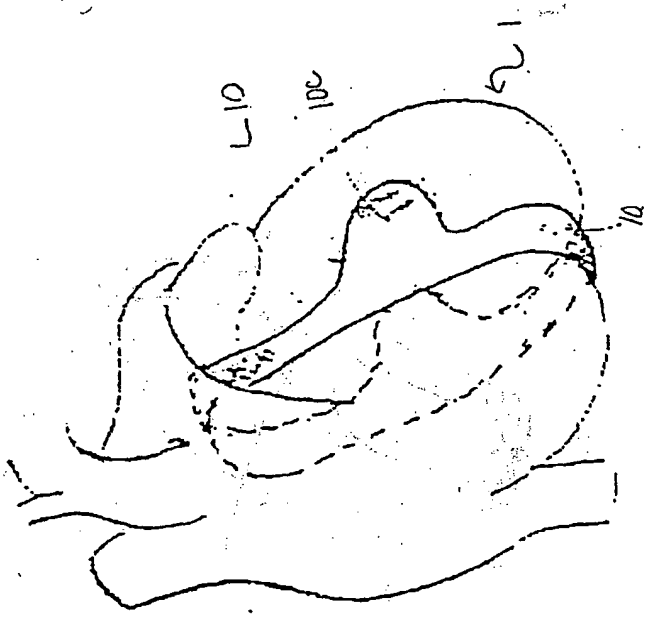


Fig. 13A

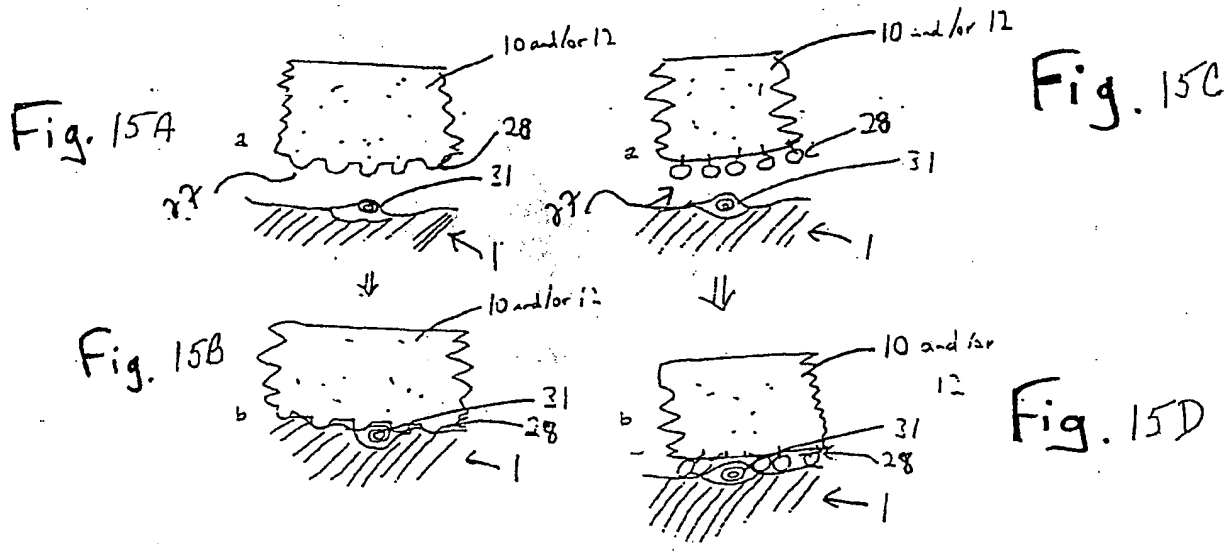


Fig. 15A

Fig. 15B

Fig. 15C

Fig. 15D

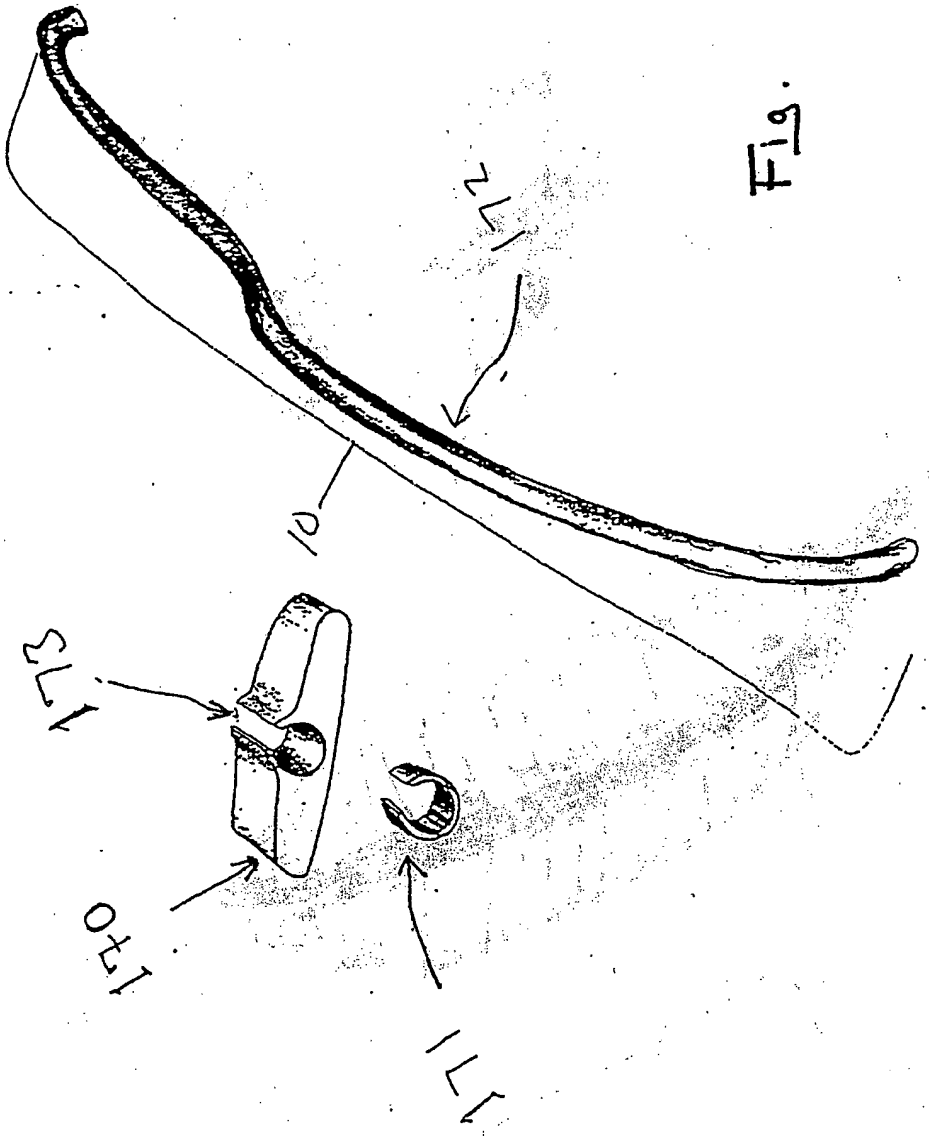


Fig. 17

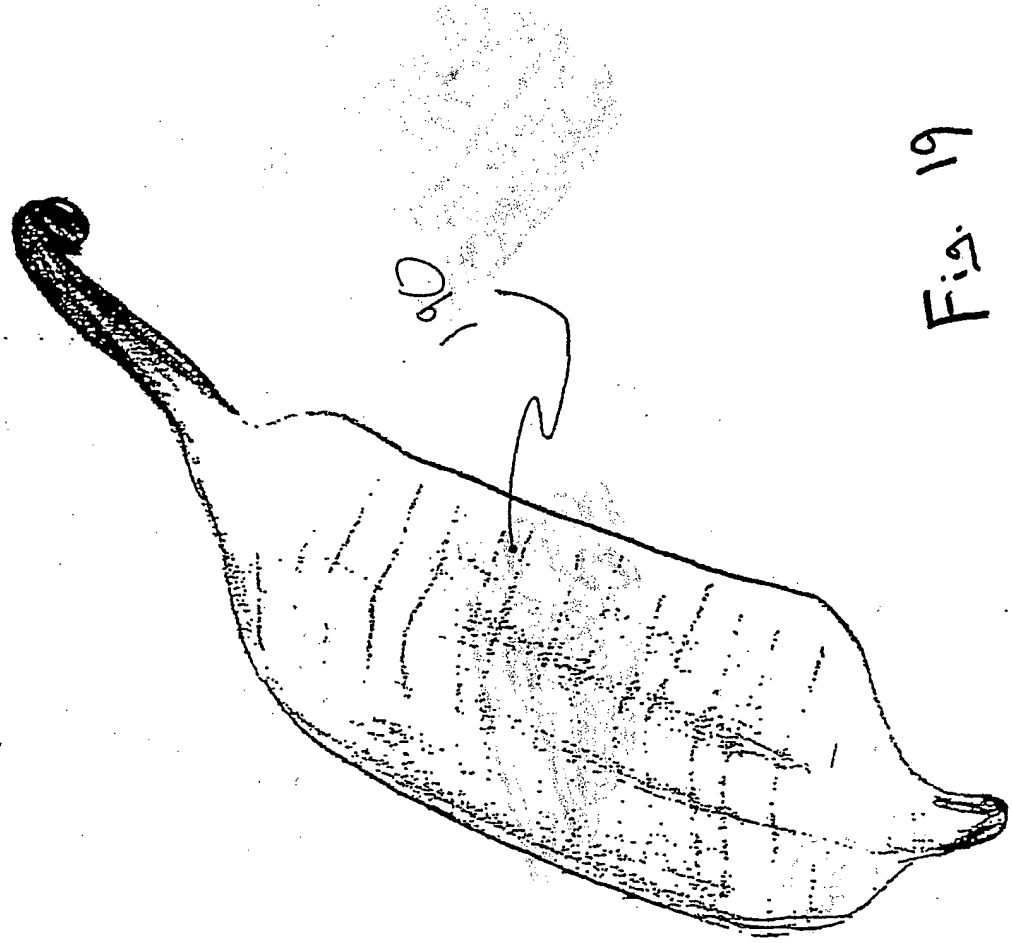


Fig 19

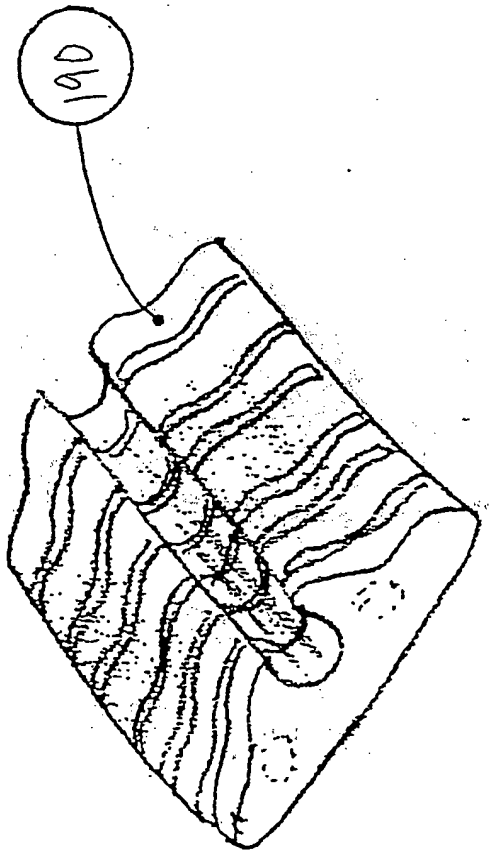


Fig. 21B

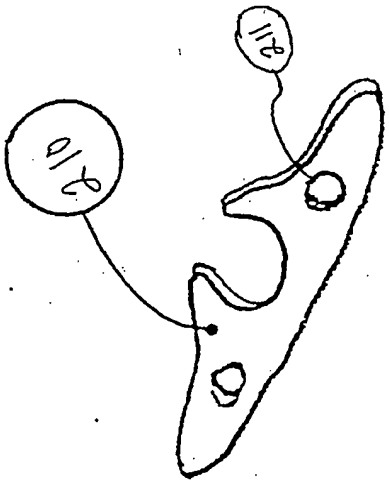


Fig. 21A

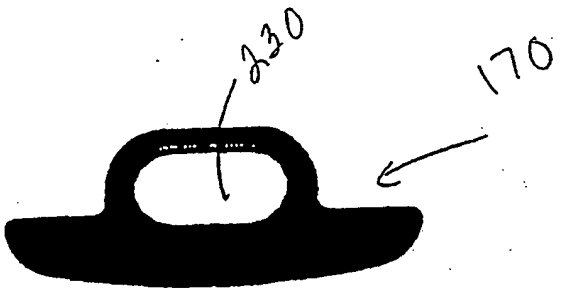


Fig. 23

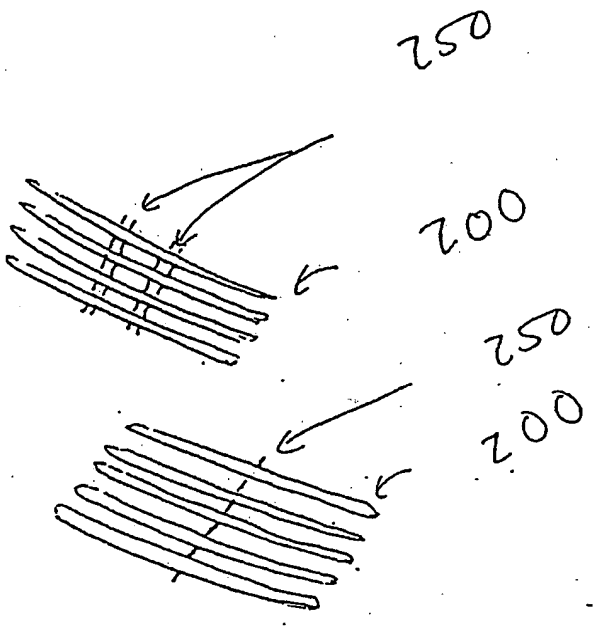


Fig. 25

Fig. 28

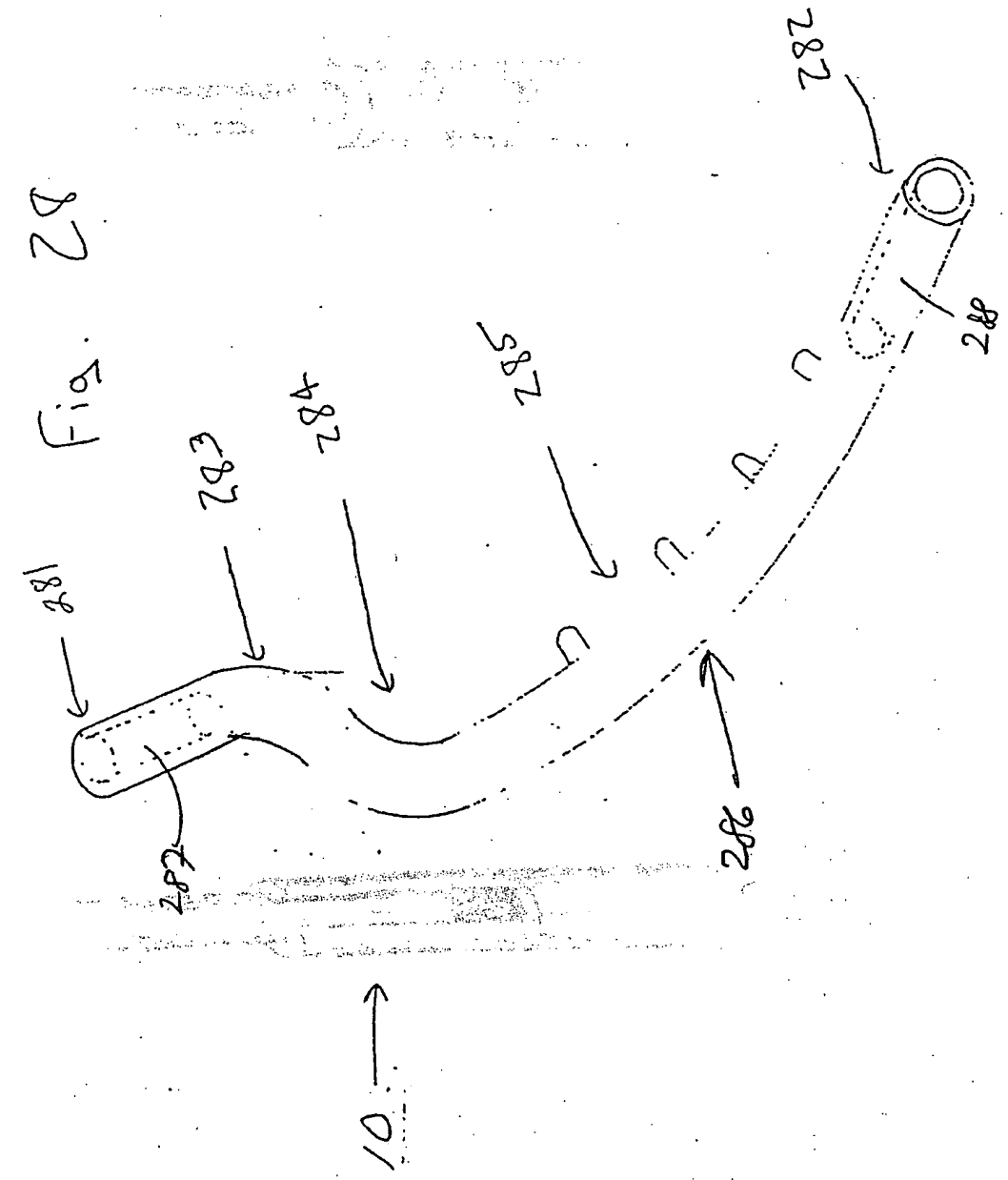
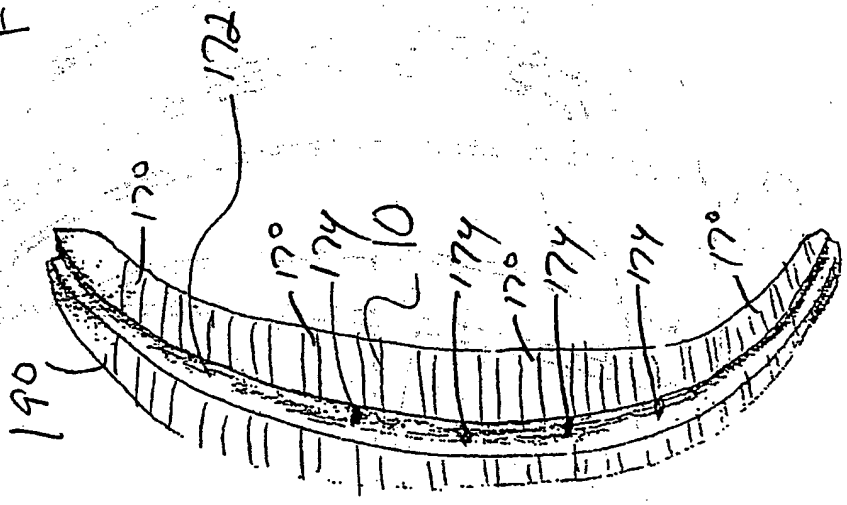


Fig. 31



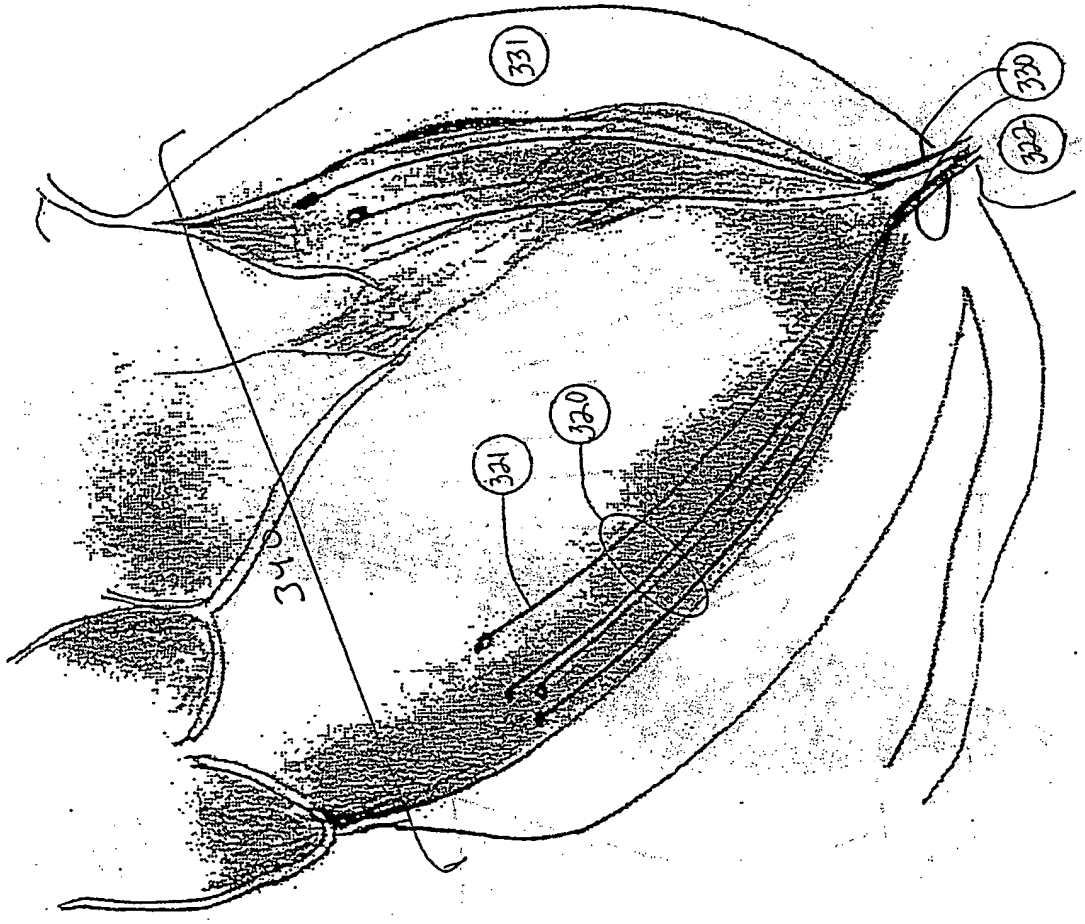


Fig 33

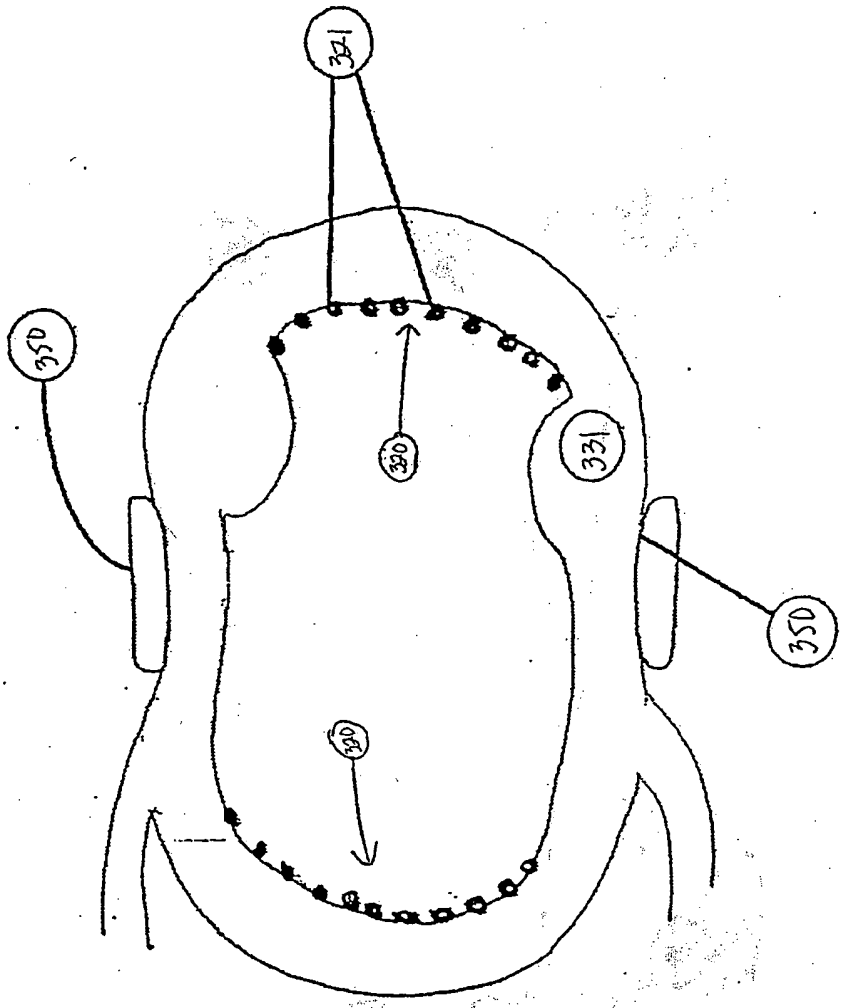


Fig 25

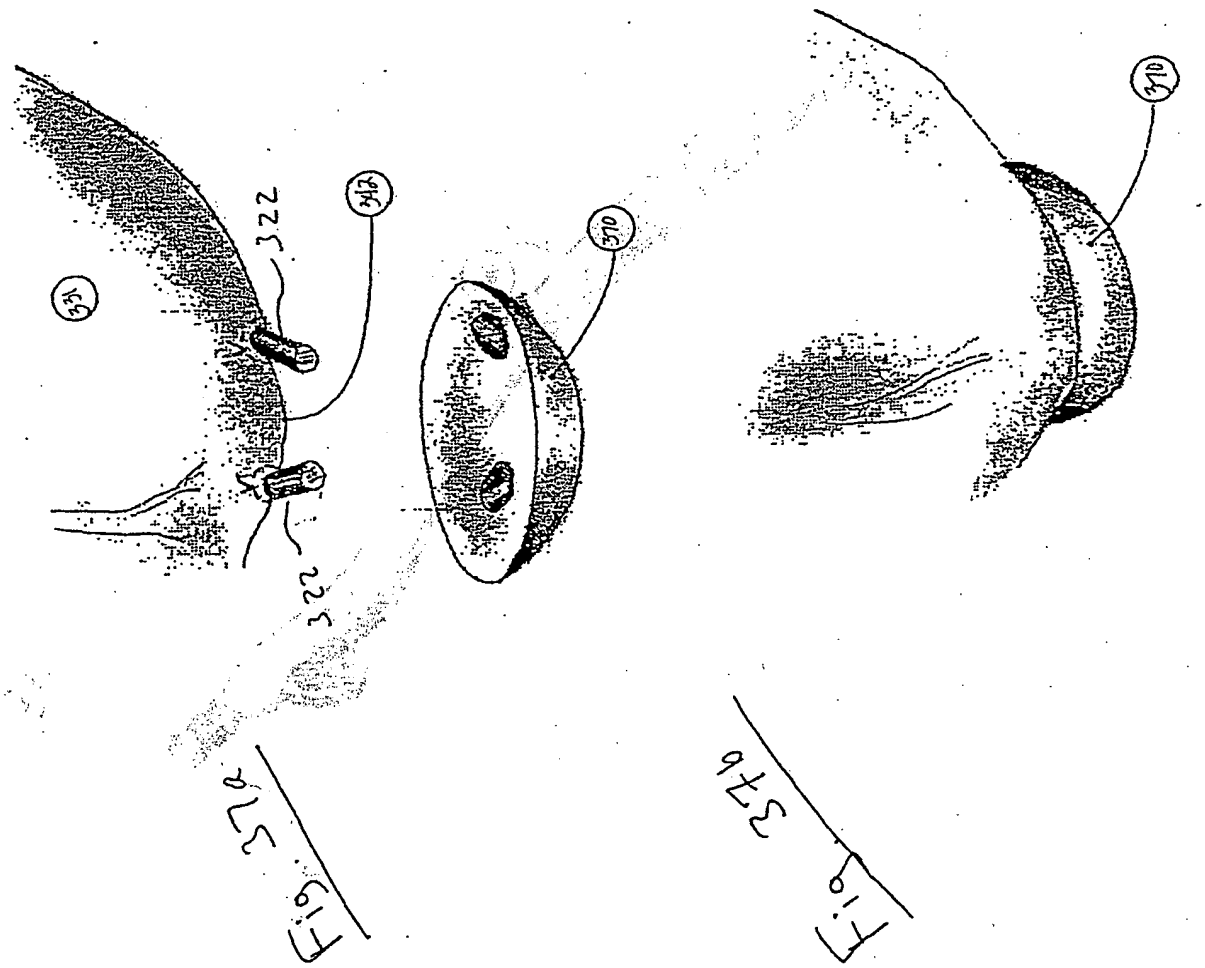


Fig. 37a

Fig. 37b

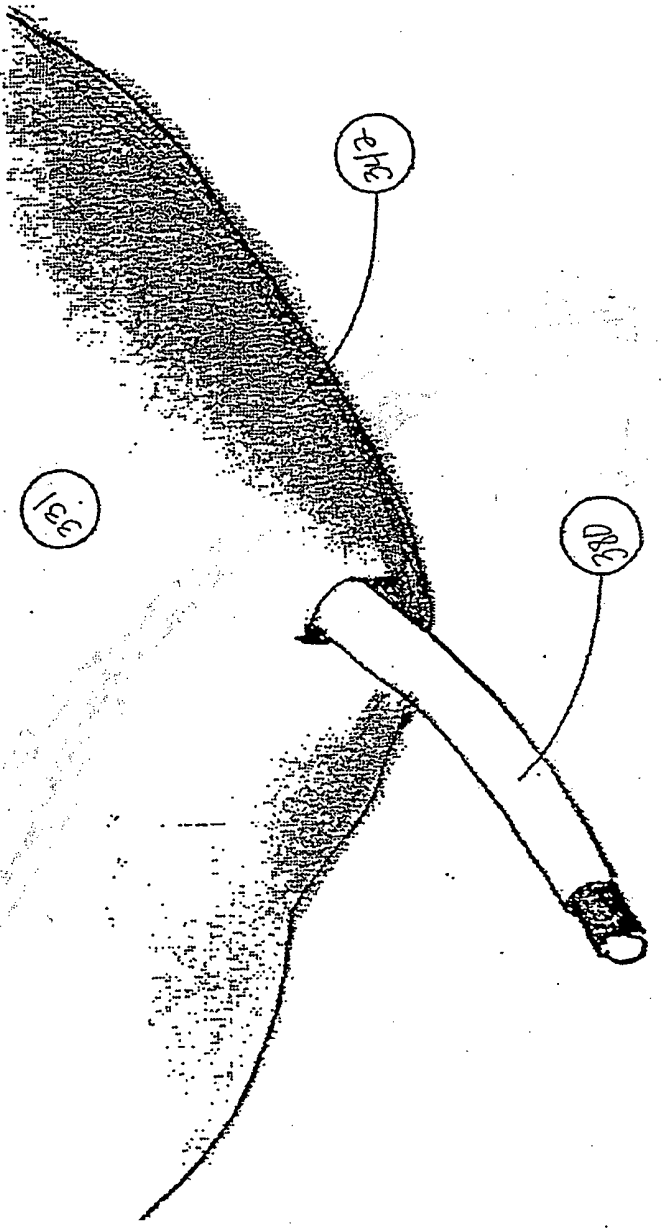


Fig. 3A

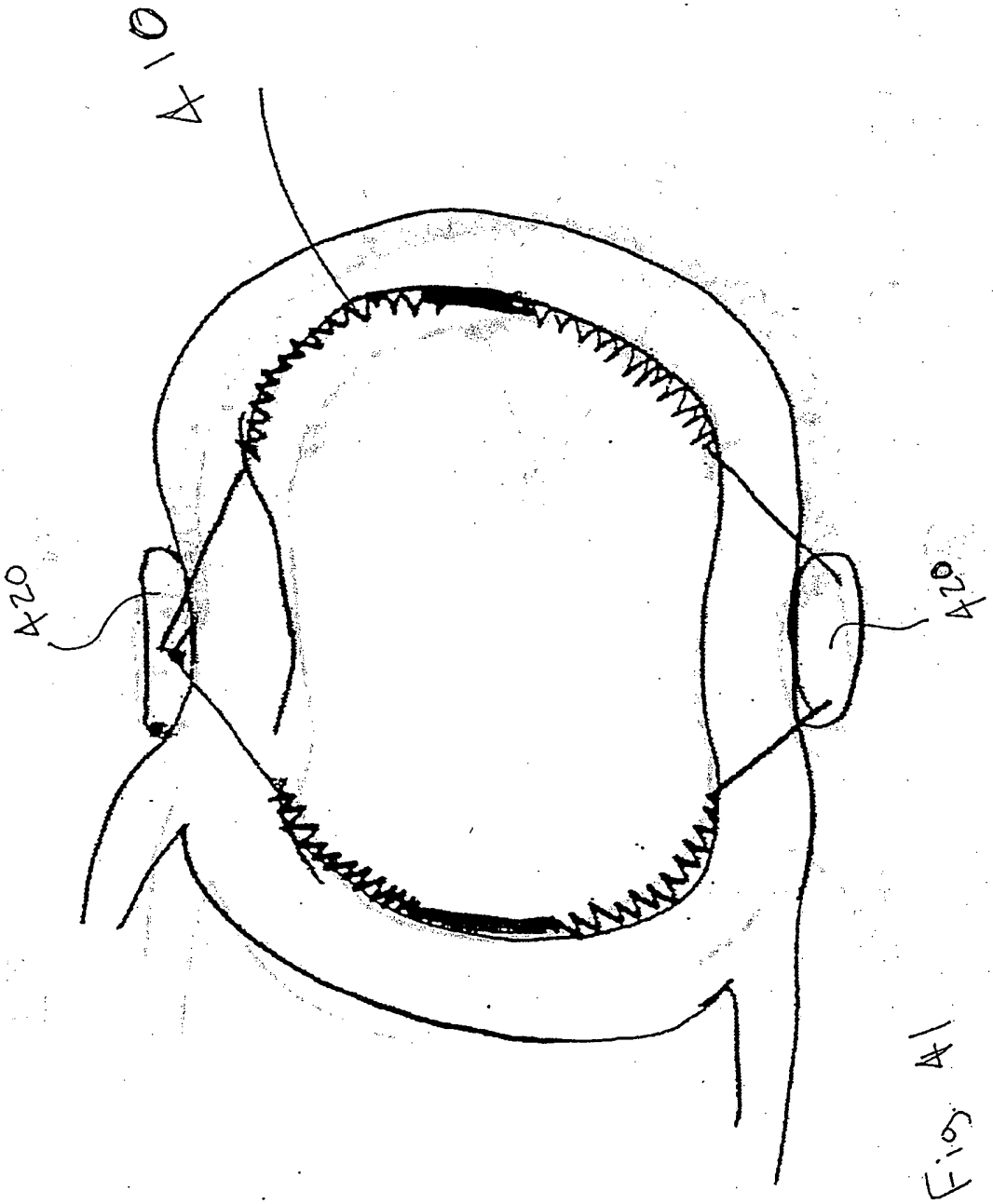


Fig. 41

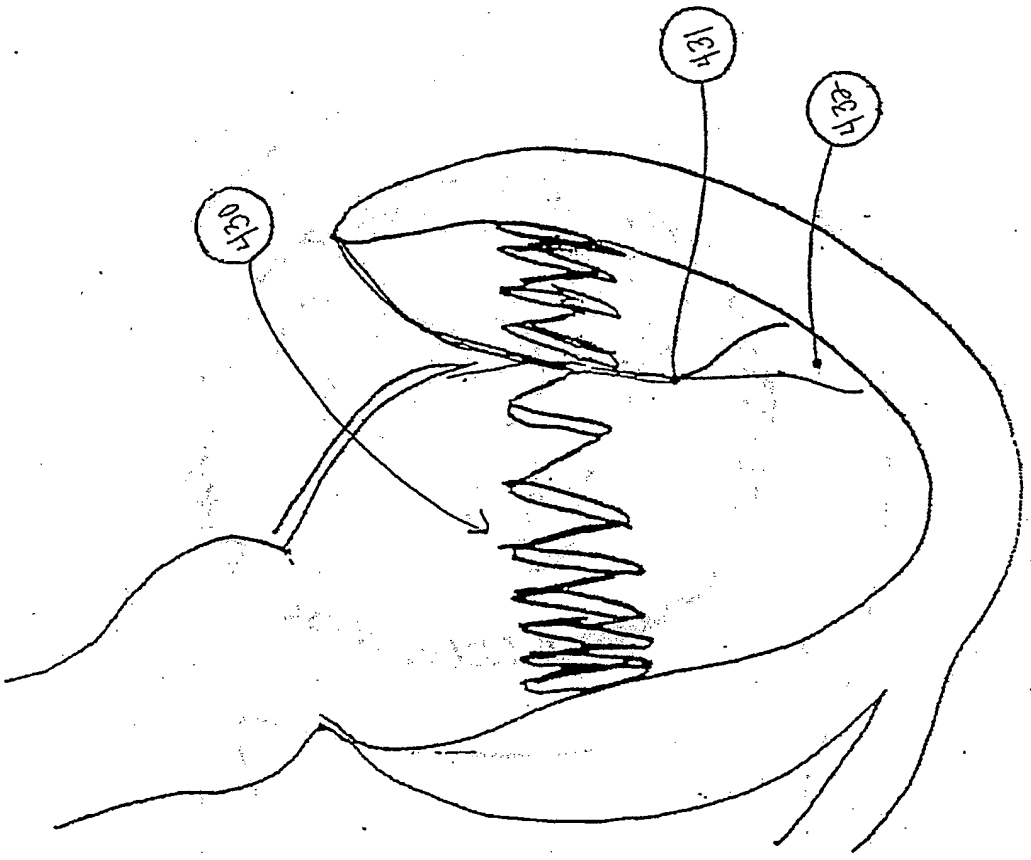


Fig 43

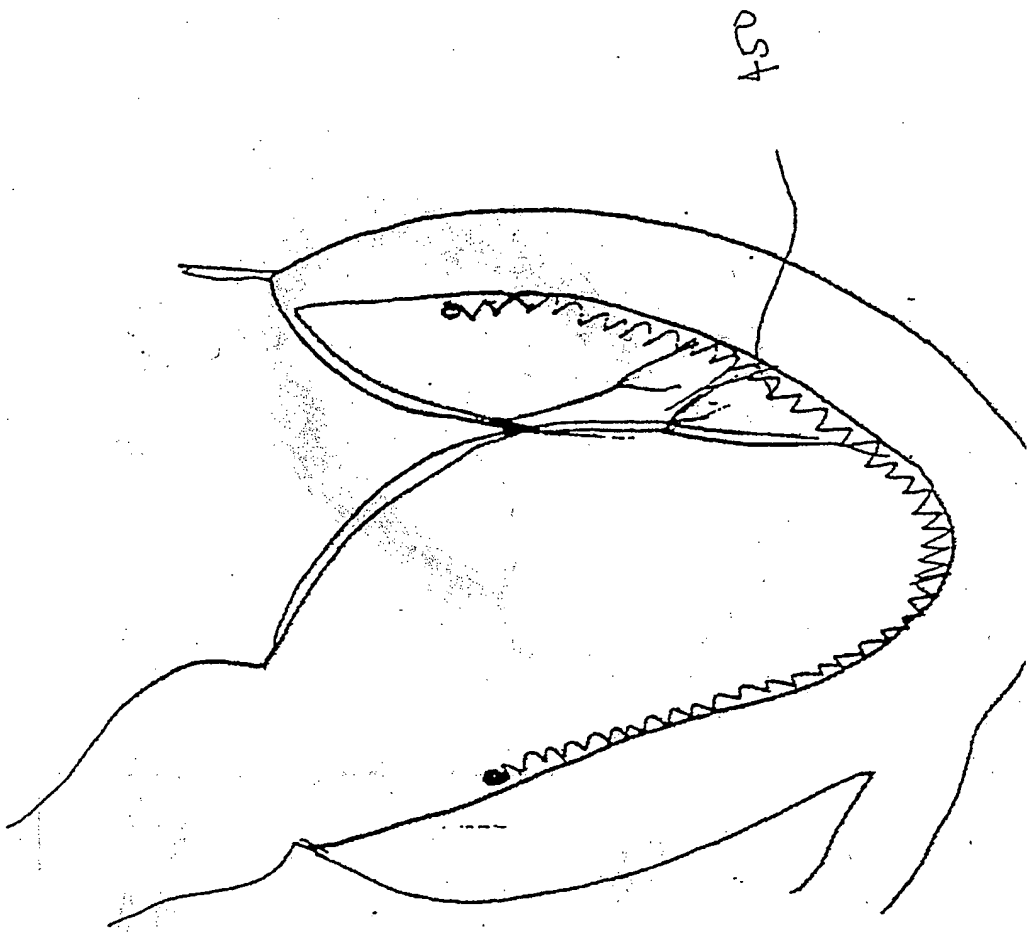


Fig. 7

Fig. 47B

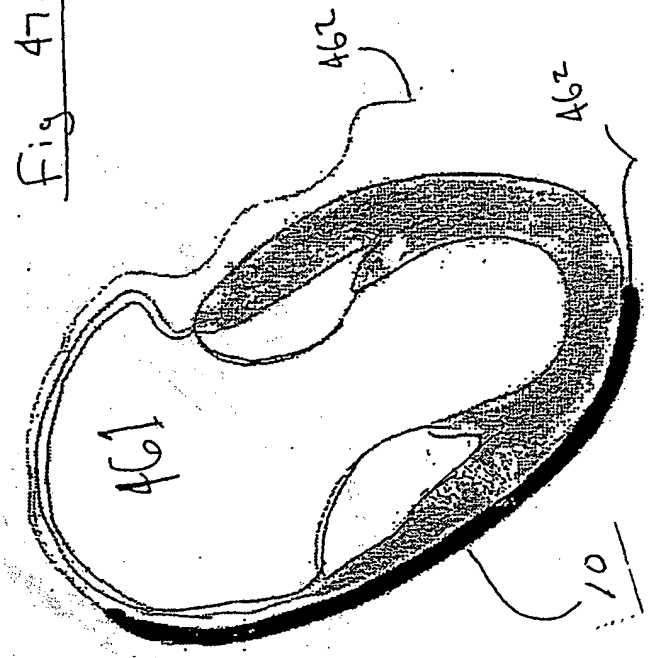


Fig. 47A

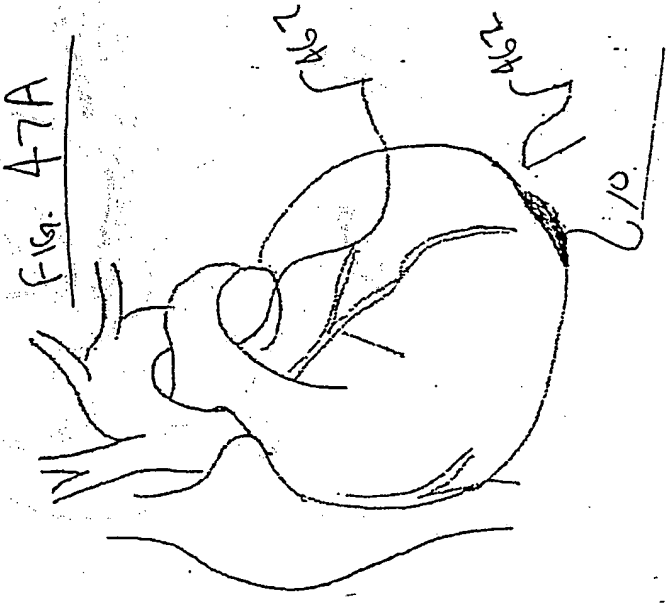


Fig. 49B

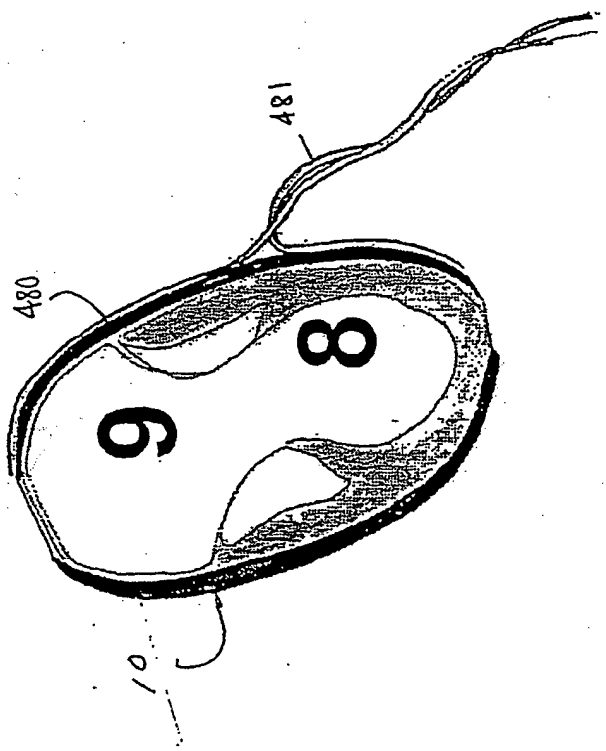
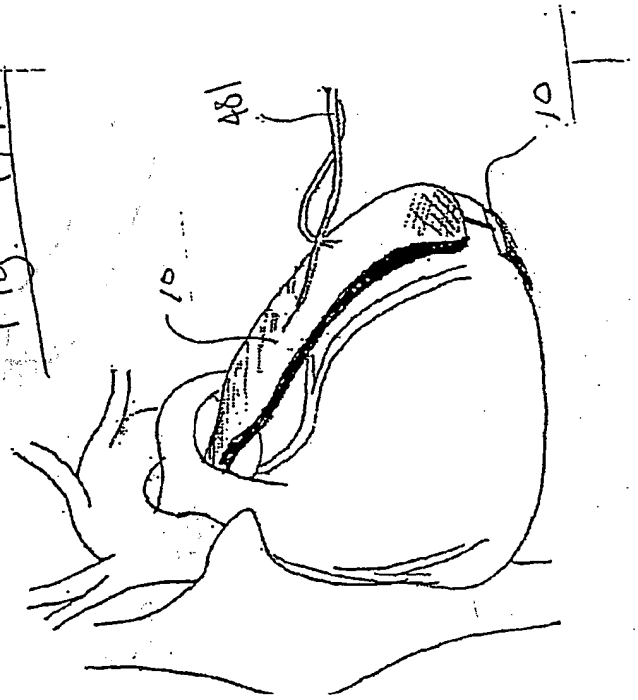


Fig. 49A



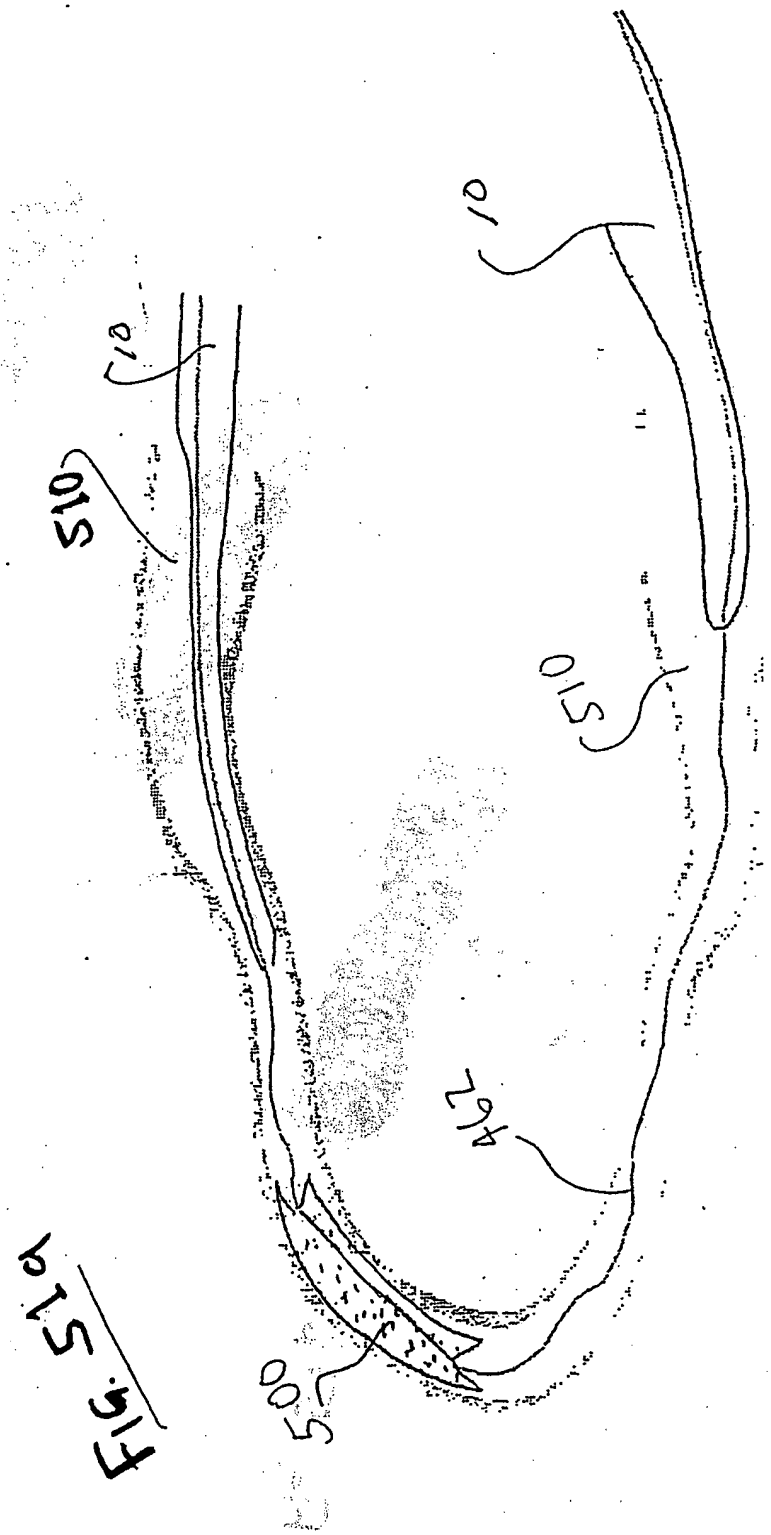


Fig. 51A

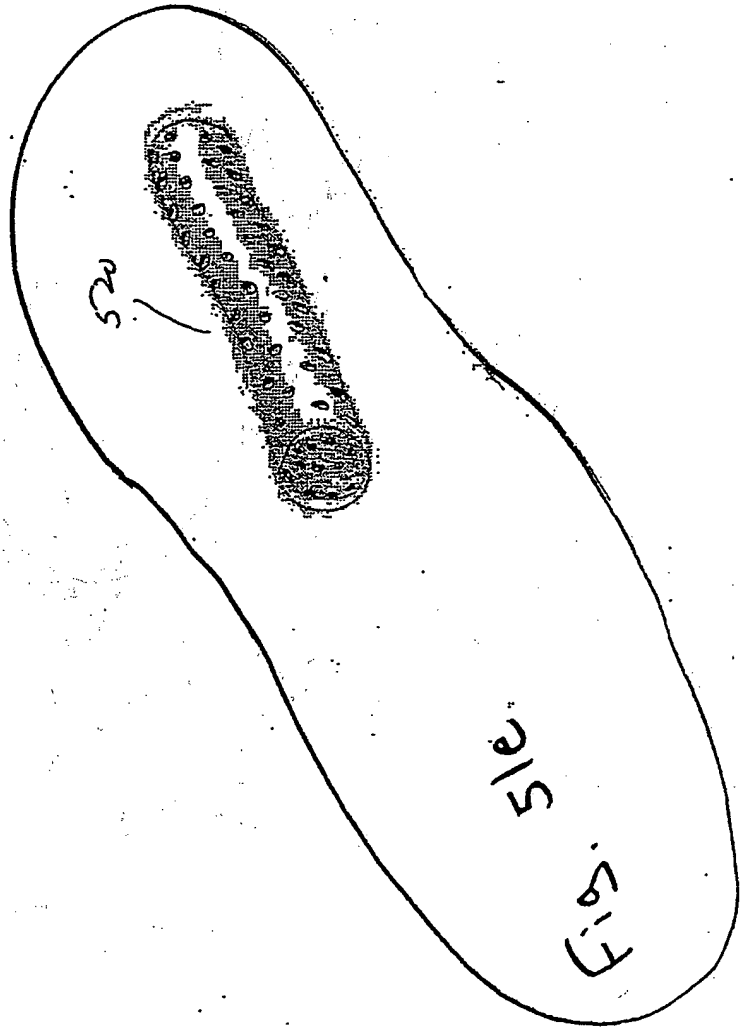

520
Fig. 5A

Fig. 53

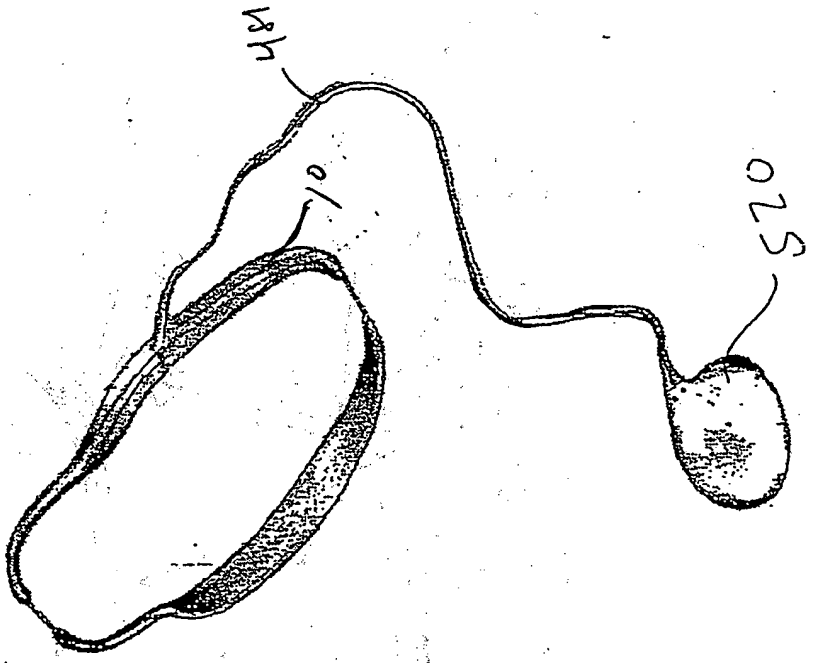


Fig. 54C

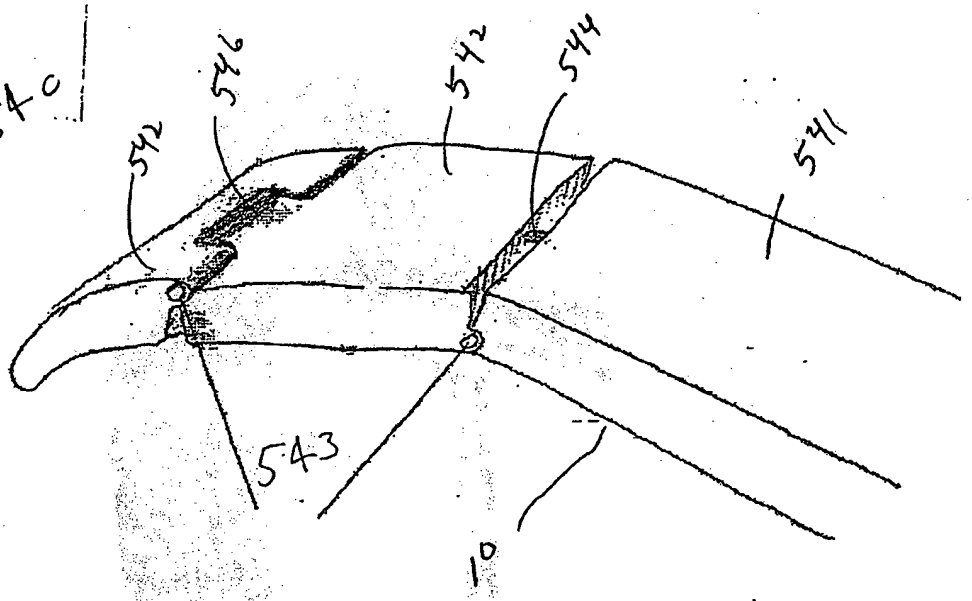
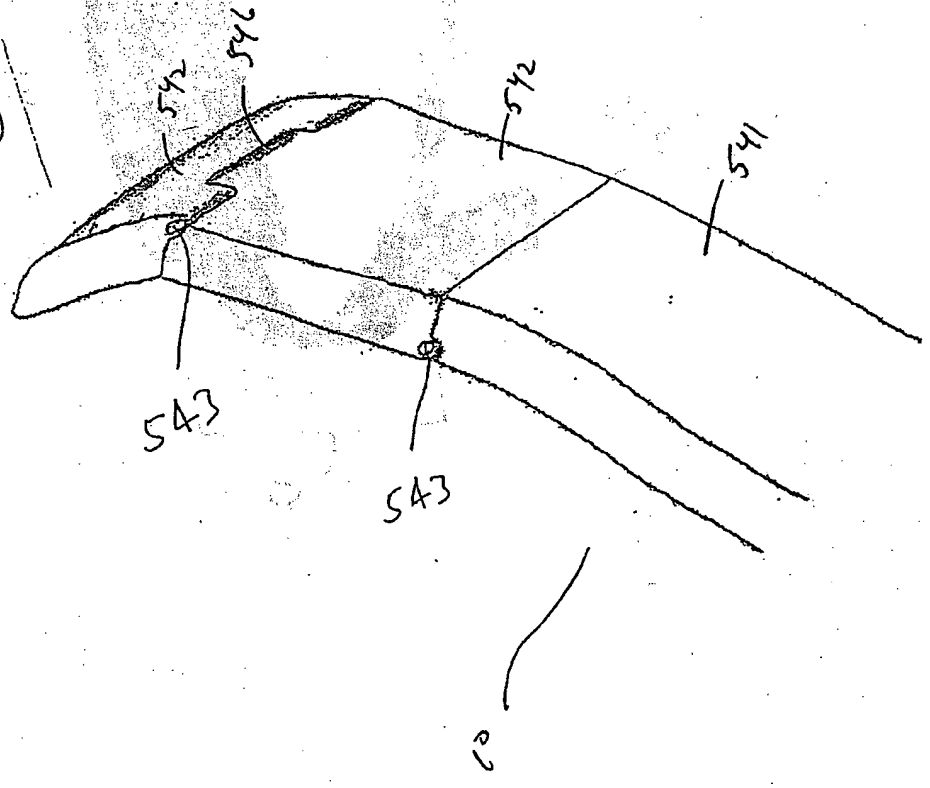


Fig. 54D



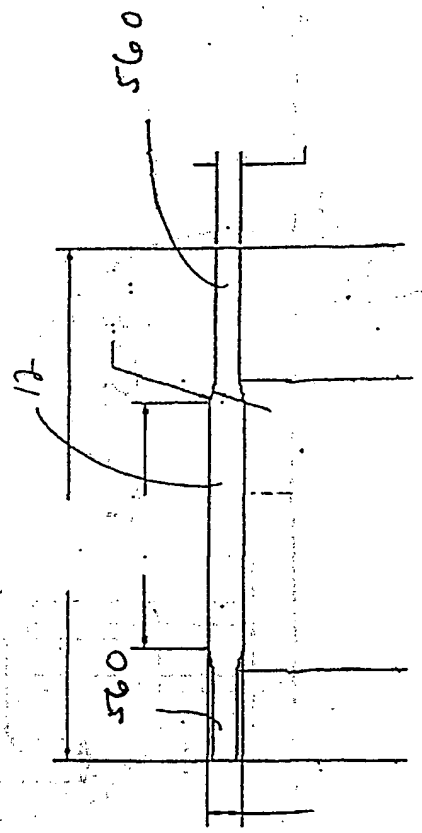


Fig. 56

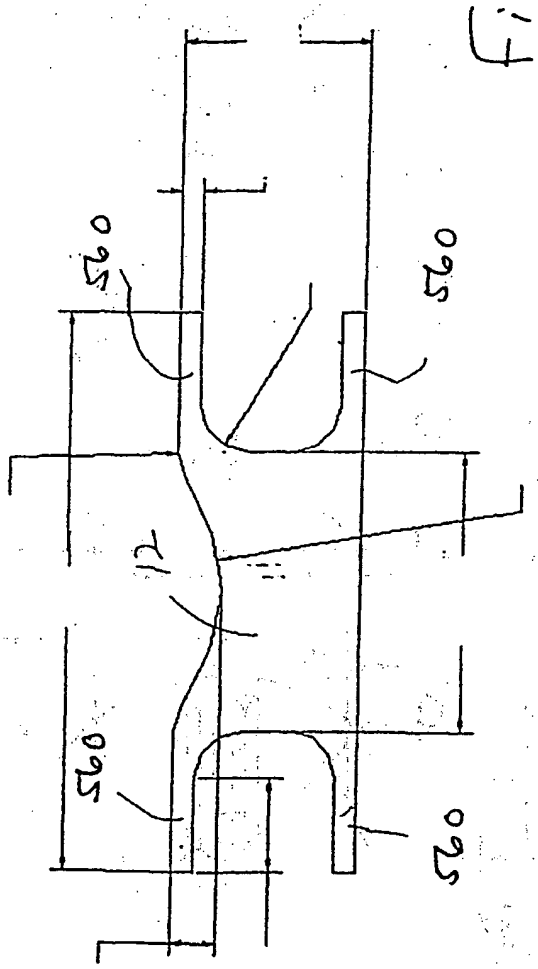


Fig. 58

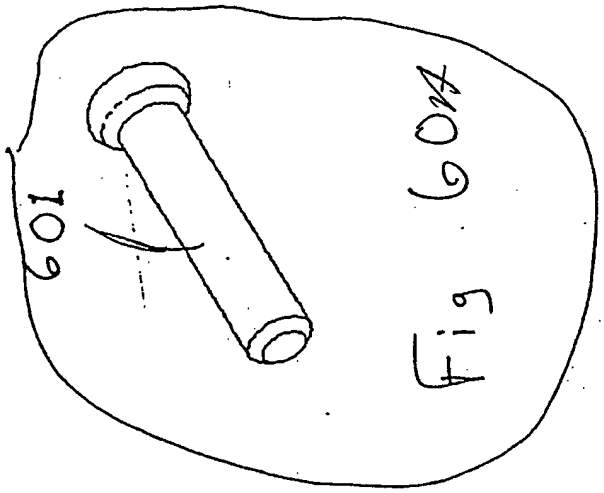


Fig 601A

Fig 601B

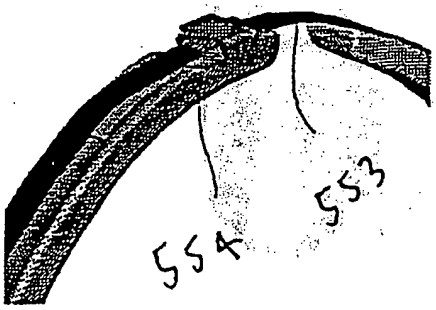


Fig. 62

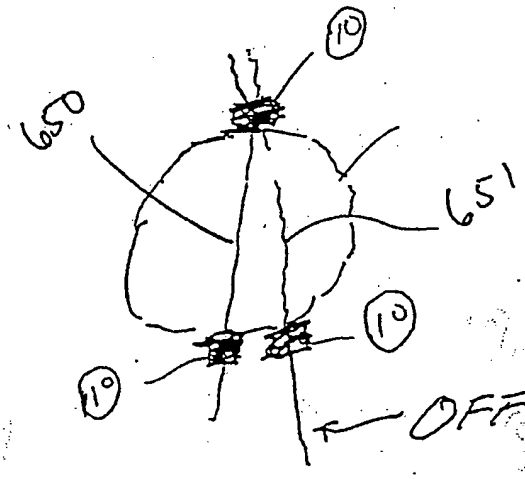


Fig. 65

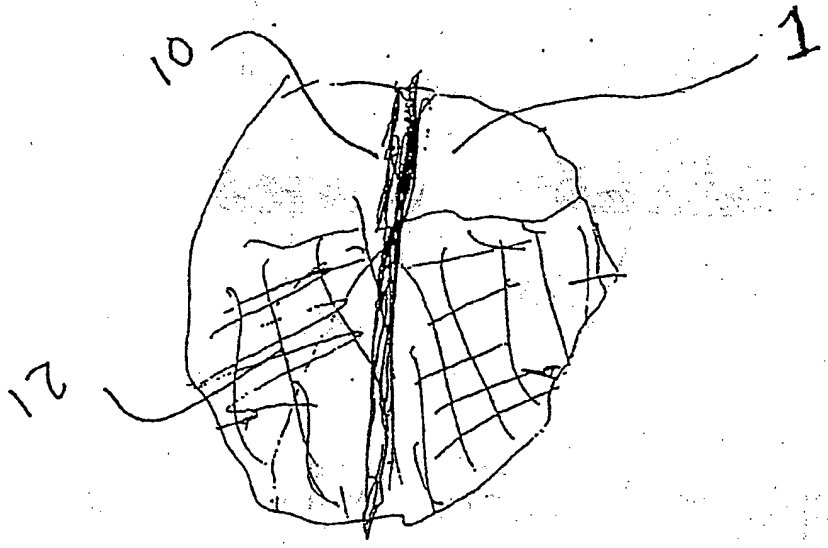


Fig. 67

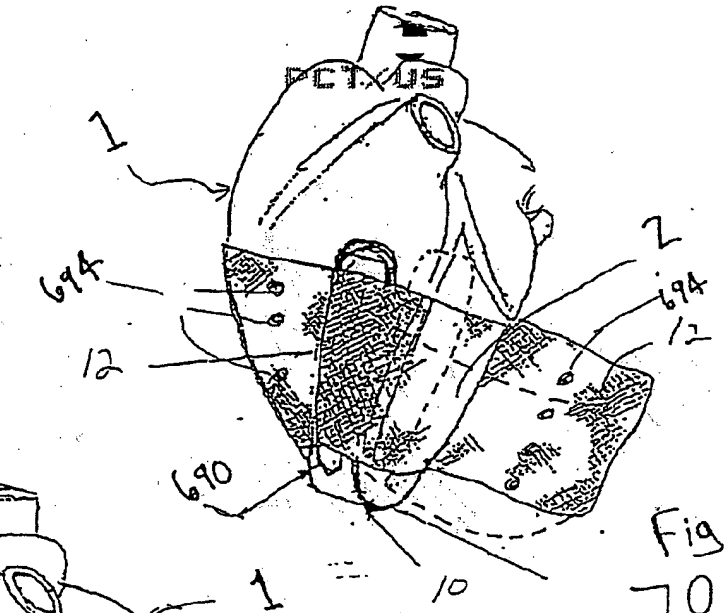


Fig. 70

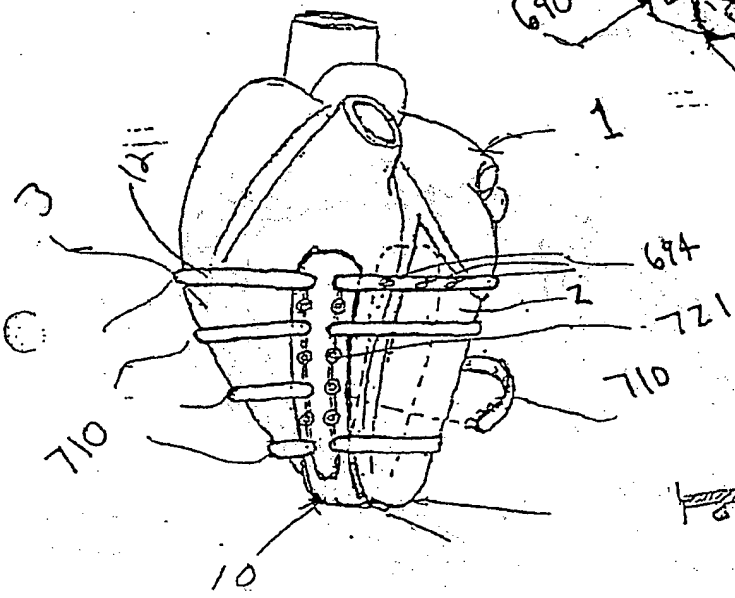


Fig. 71

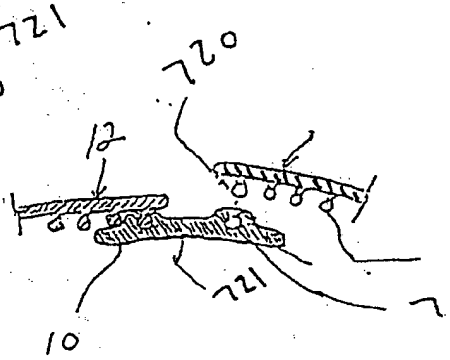


Fig. 72

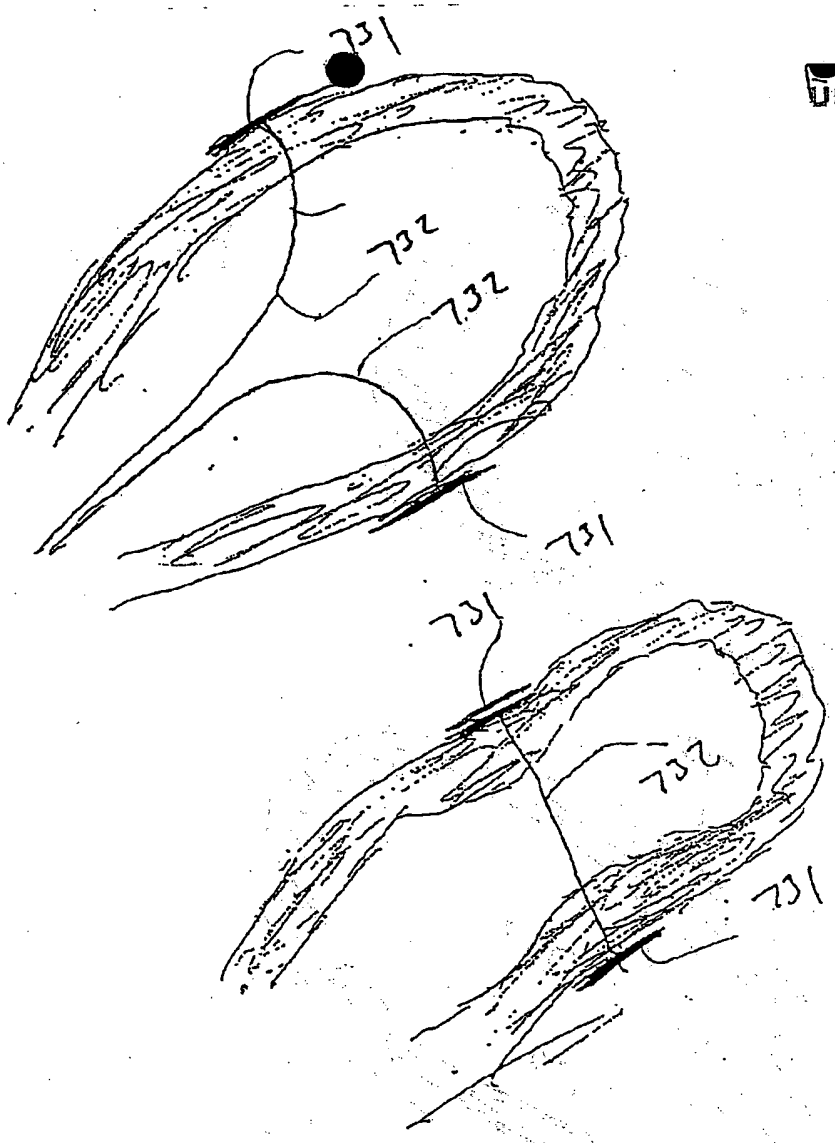


Fig. 74a

Fig. 74b

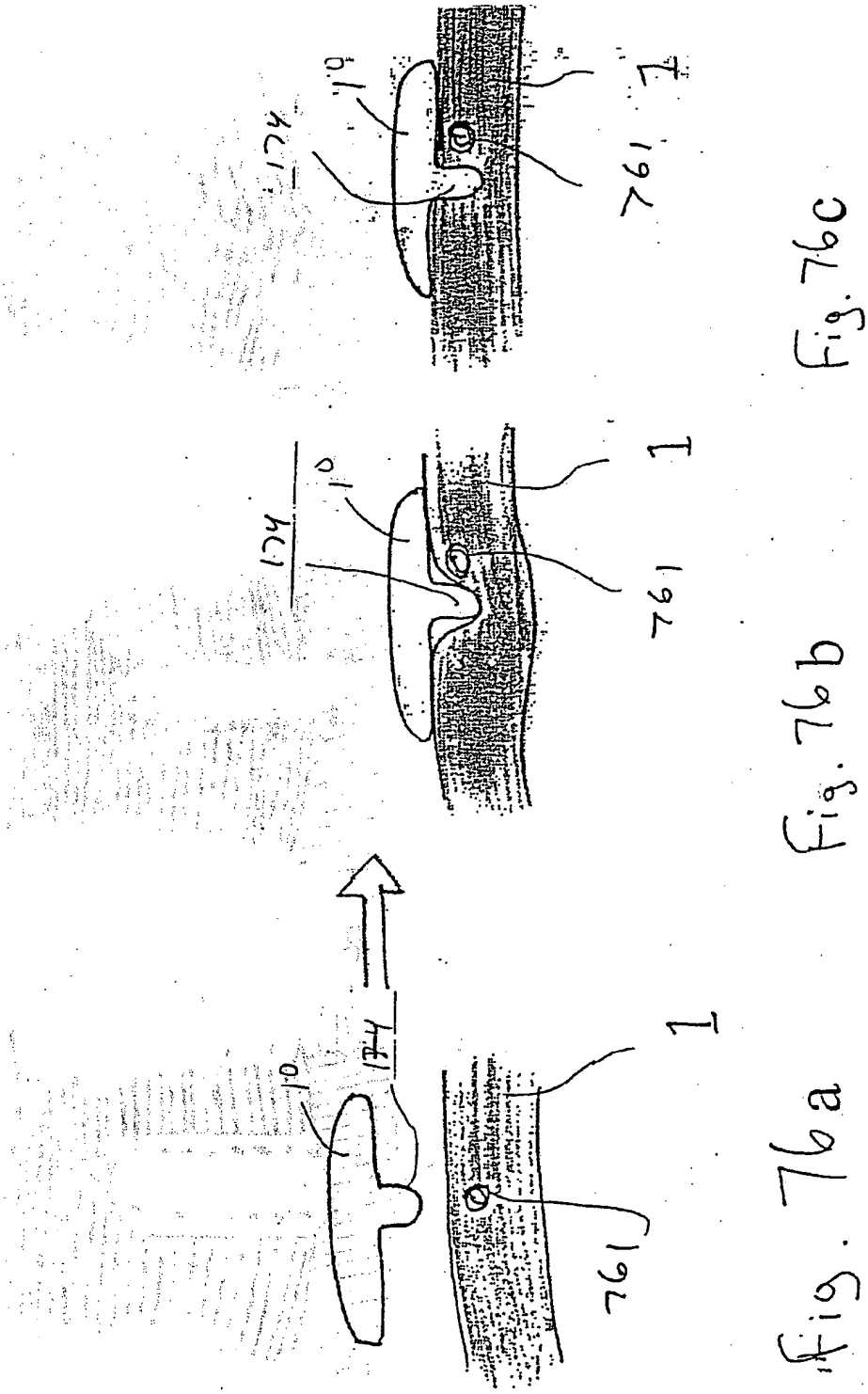


Fig. 76a

Fig. 76b

Fig. 76c

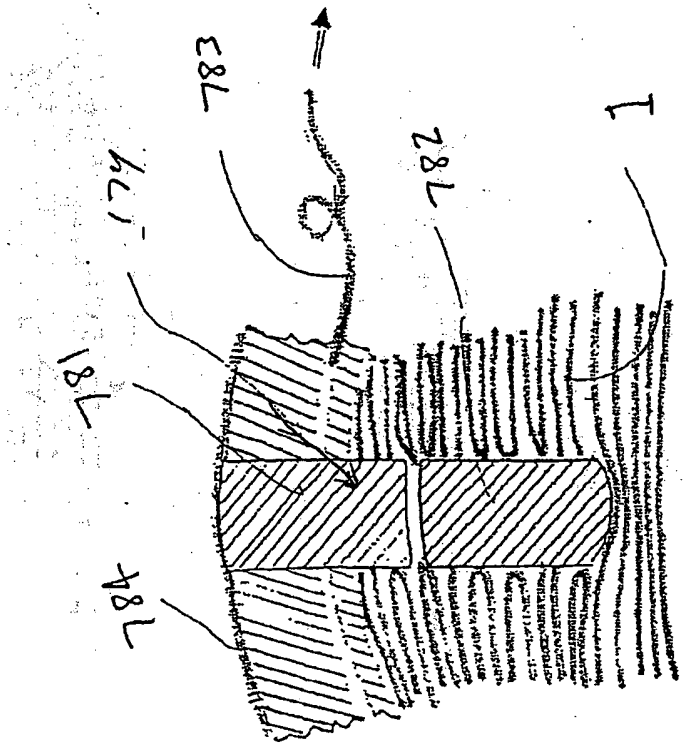


Fig. 78 b

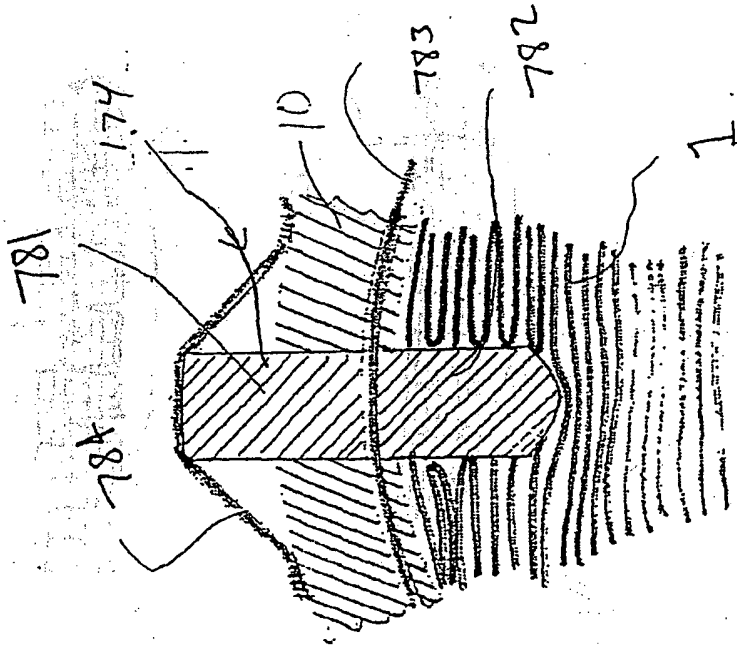


Fig. 78 a

Fig. 80b

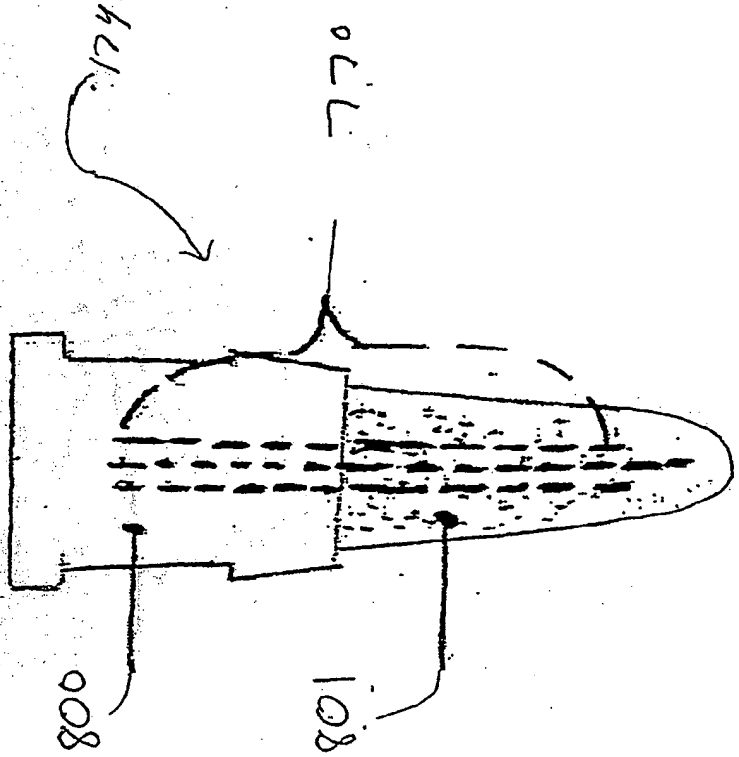
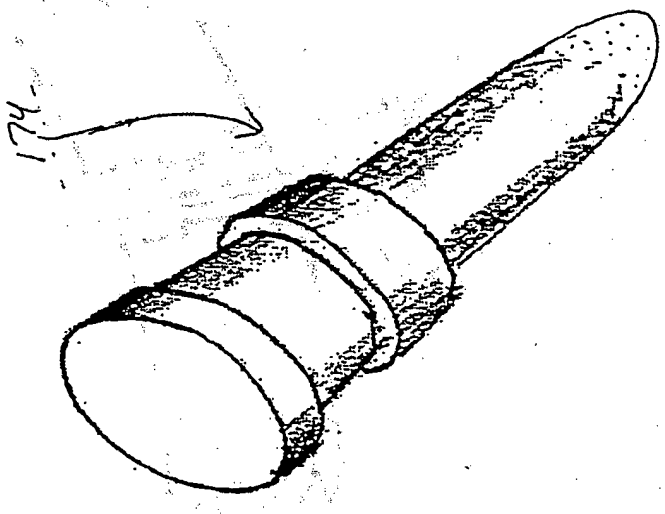


Fig. 80a



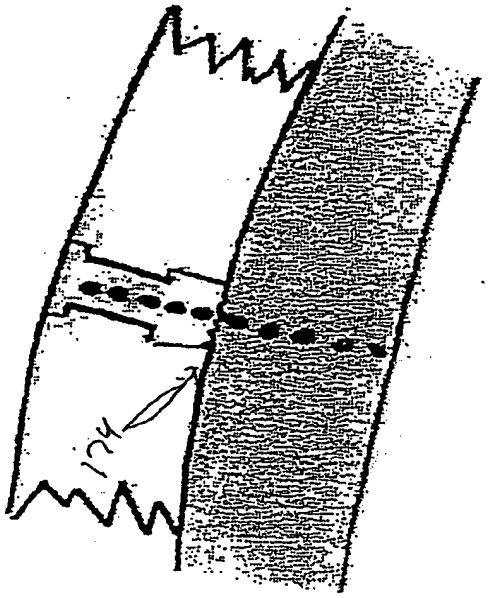


Fig. 87b

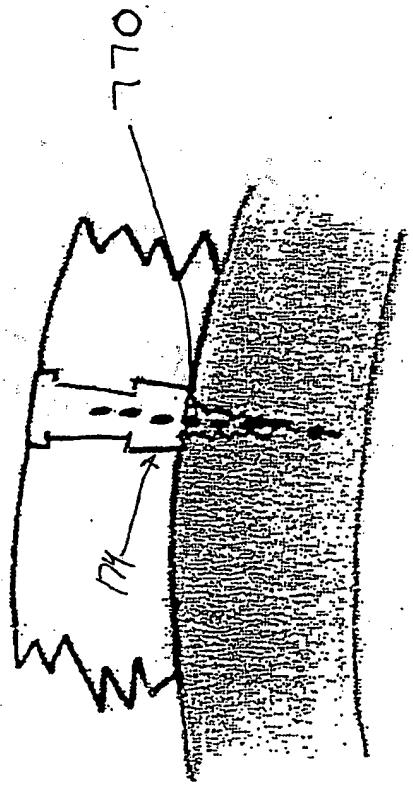


Fig. 87a

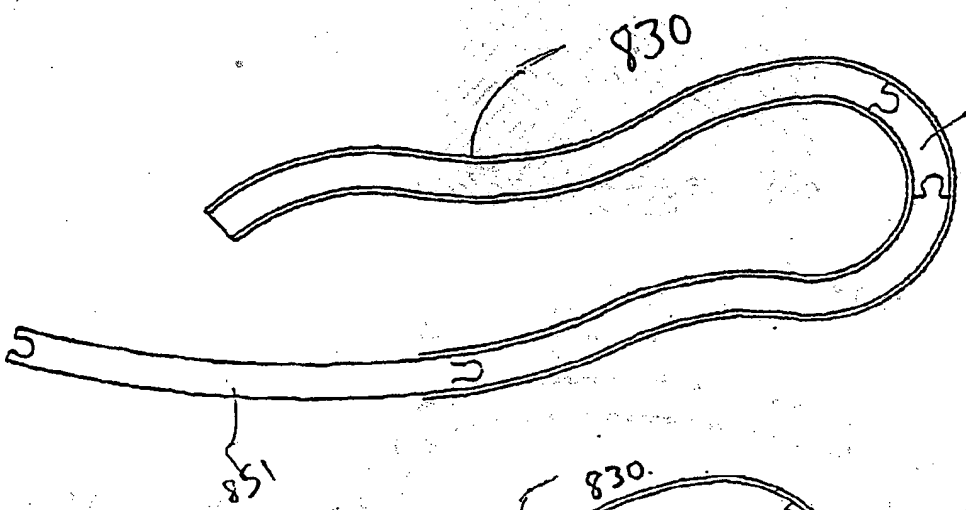


Fig. 86c

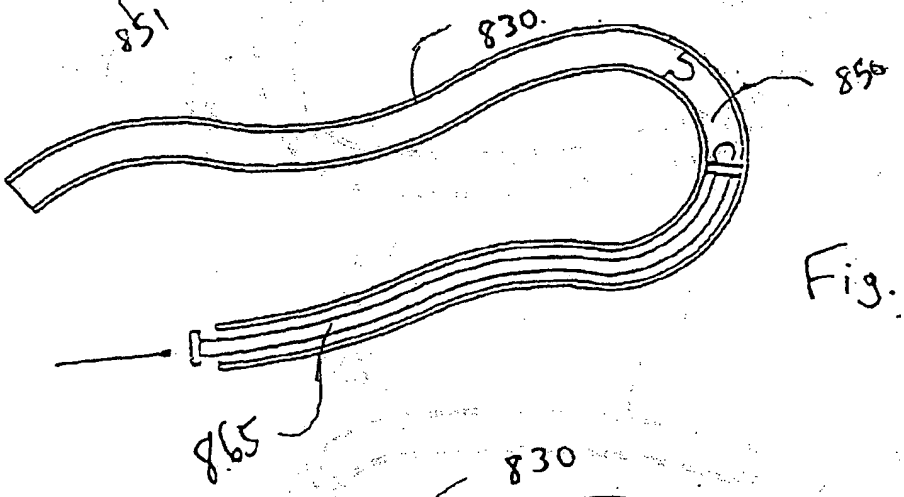


Fig. 86b

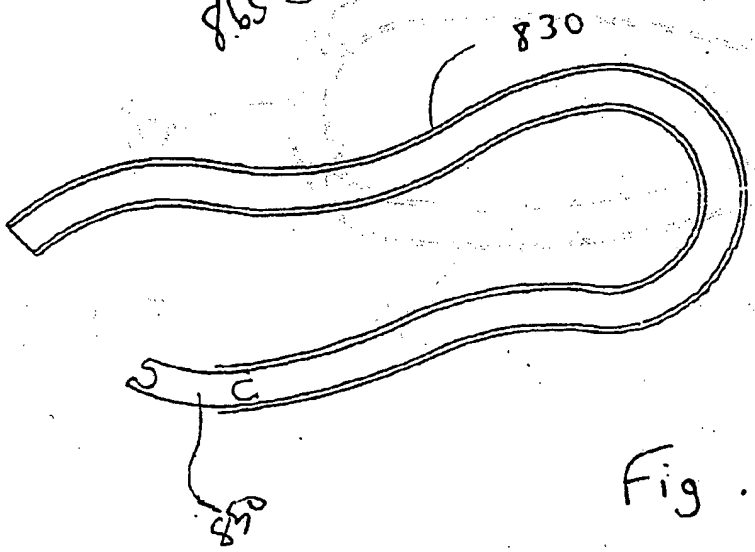


Fig. 86a

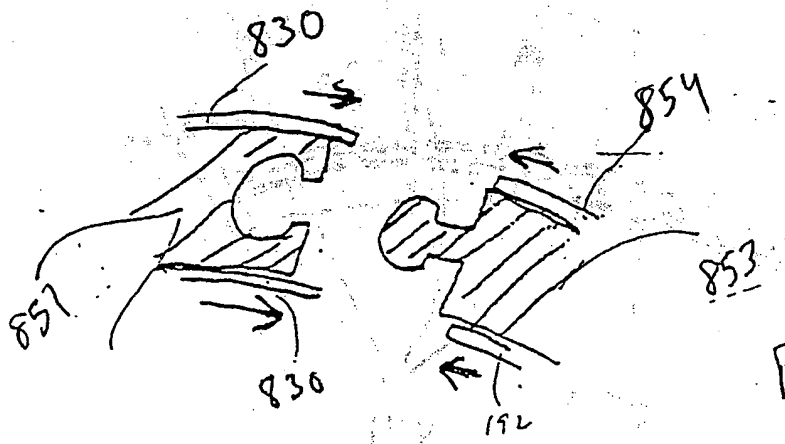


Fig. 86g

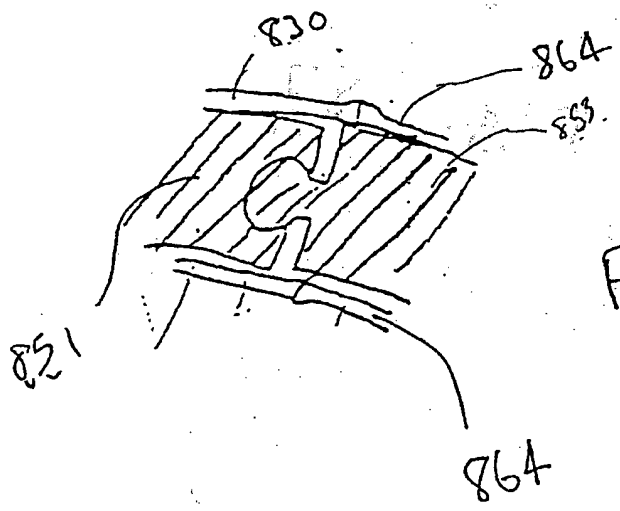


Fig. 86h

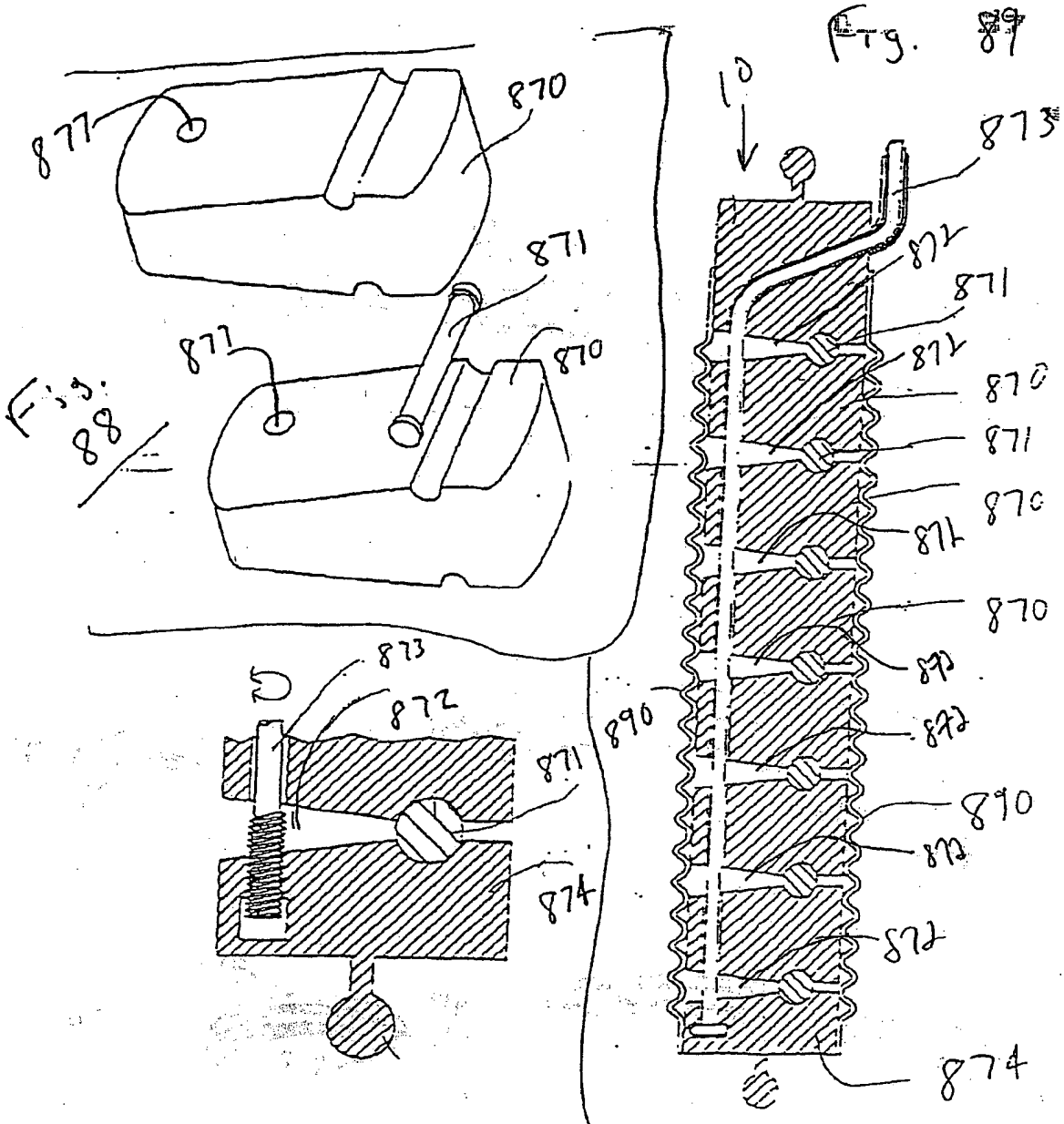
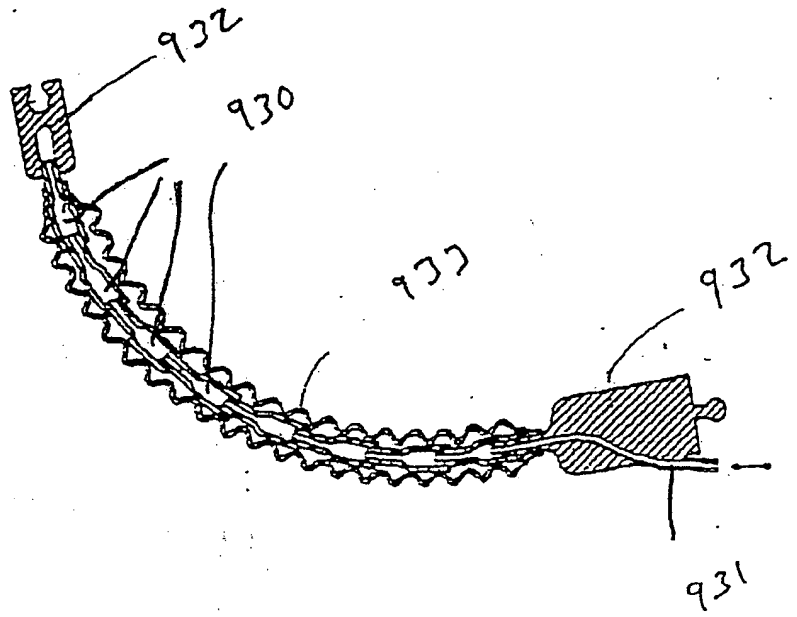


Fig. 88

Fig. 89

Fig. 90

Fig. 93a



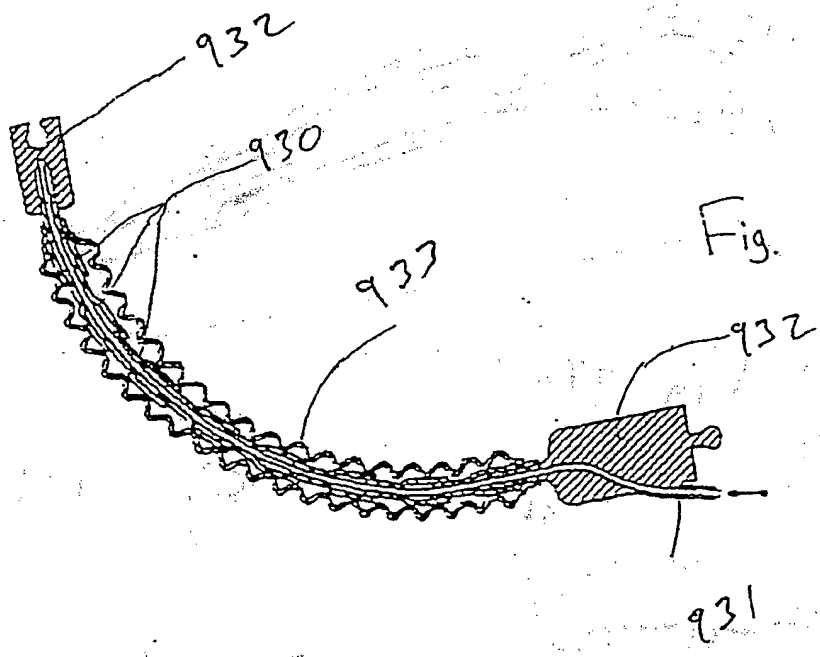


Fig. 93b

Fig. 96

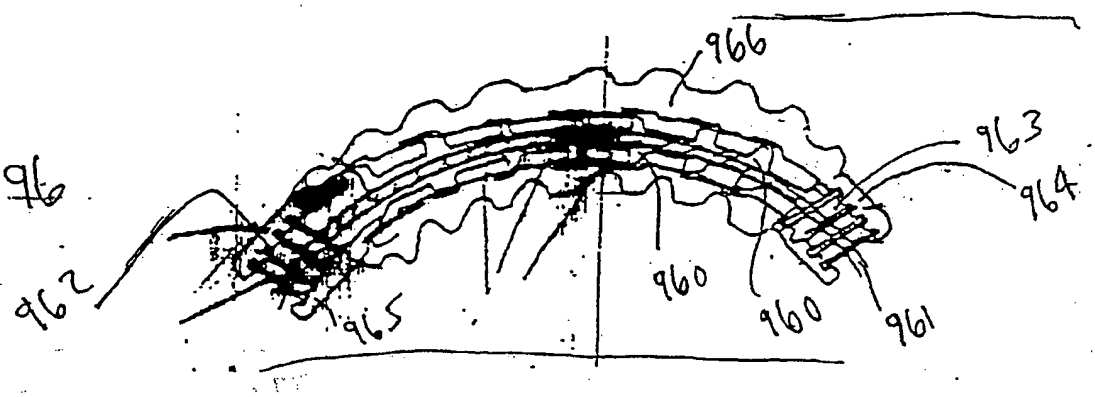


Fig. 99 a.

Fig 99b

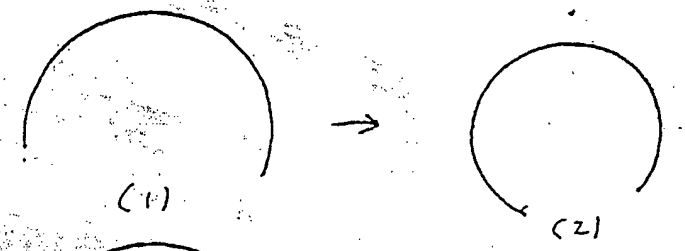


Fig. 99C

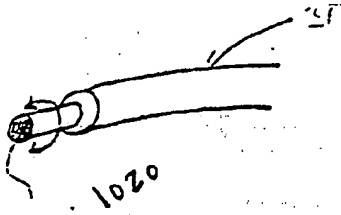


Fig. 103

PCT/US 01/17637

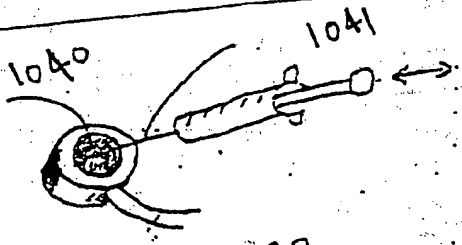


Fig. 104

Fig. 105a

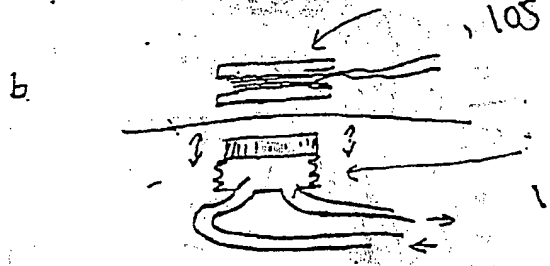


Fig. 105b

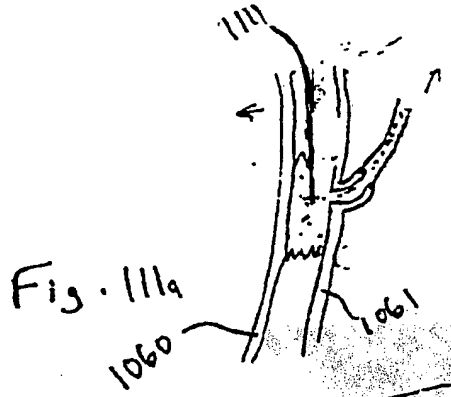


Fig. 111a

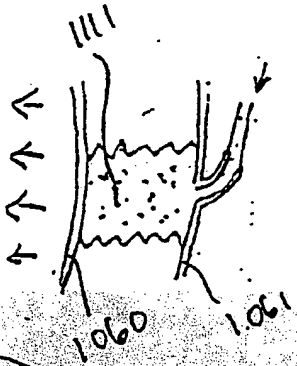


Fig. 111b

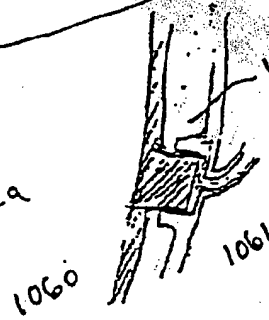


Fig. 112a

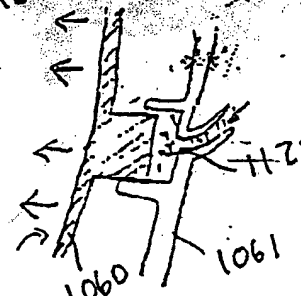


Fig. 112b

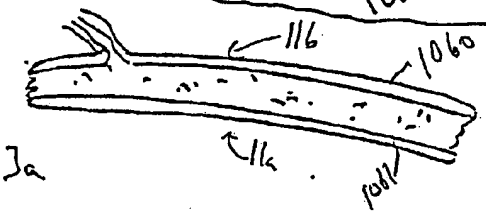


Fig. 113a

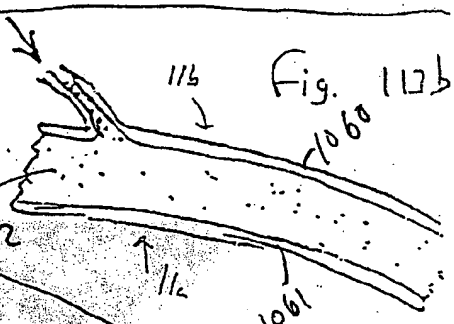


Fig. 113b

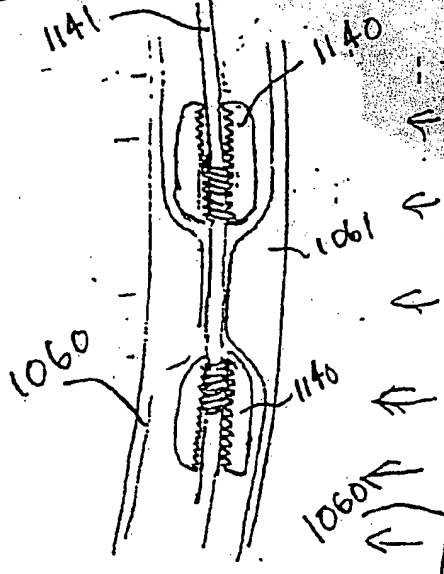


Fig. 114a

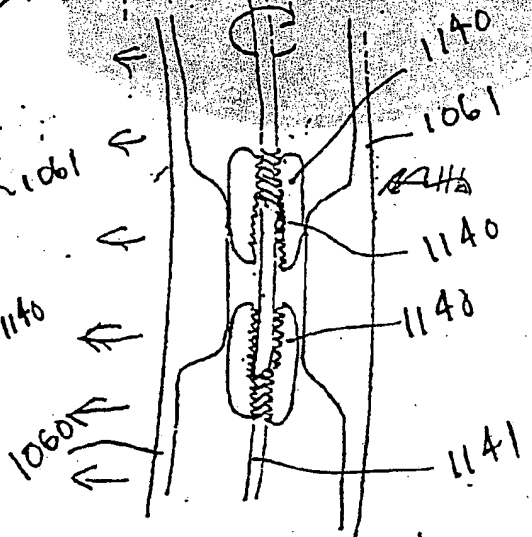


Fig. 114b

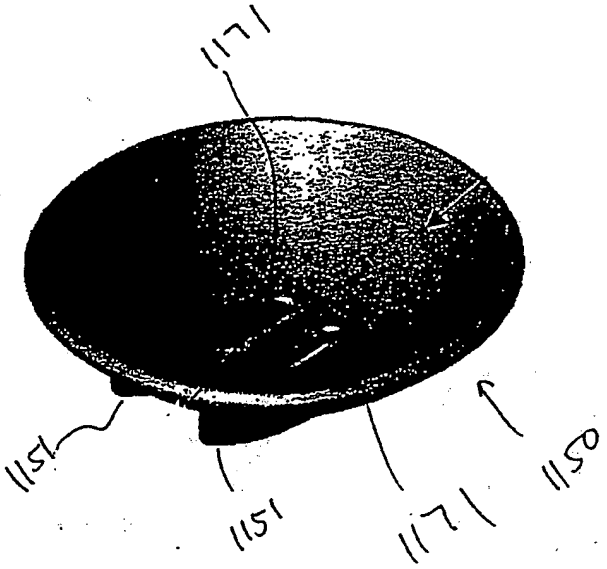


Fig 117

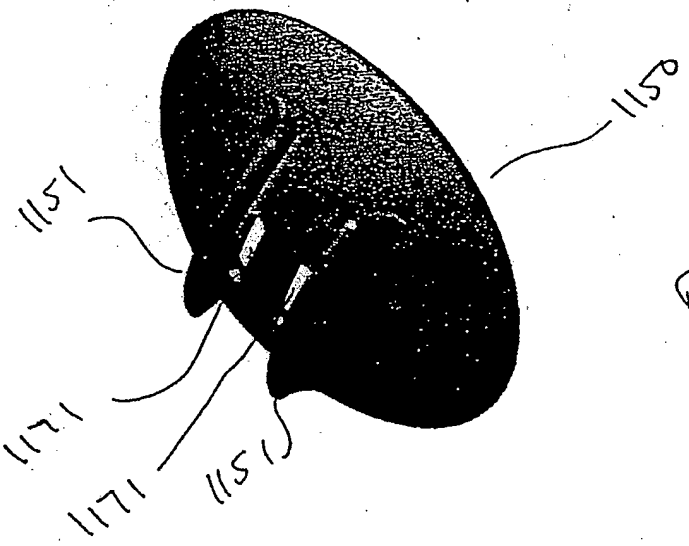


Fig. 118

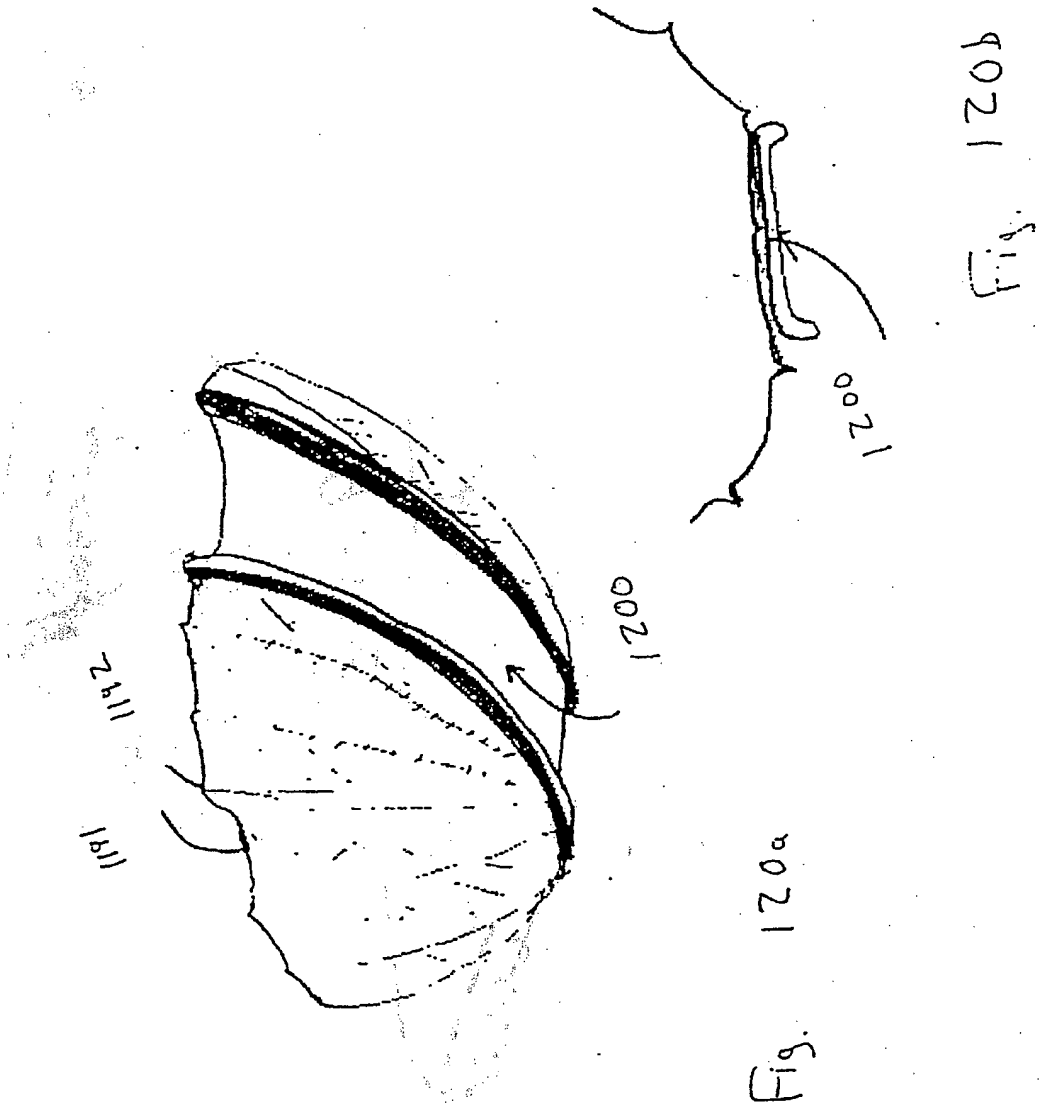


Fig. 120

Fig. 120A

Fig. 122

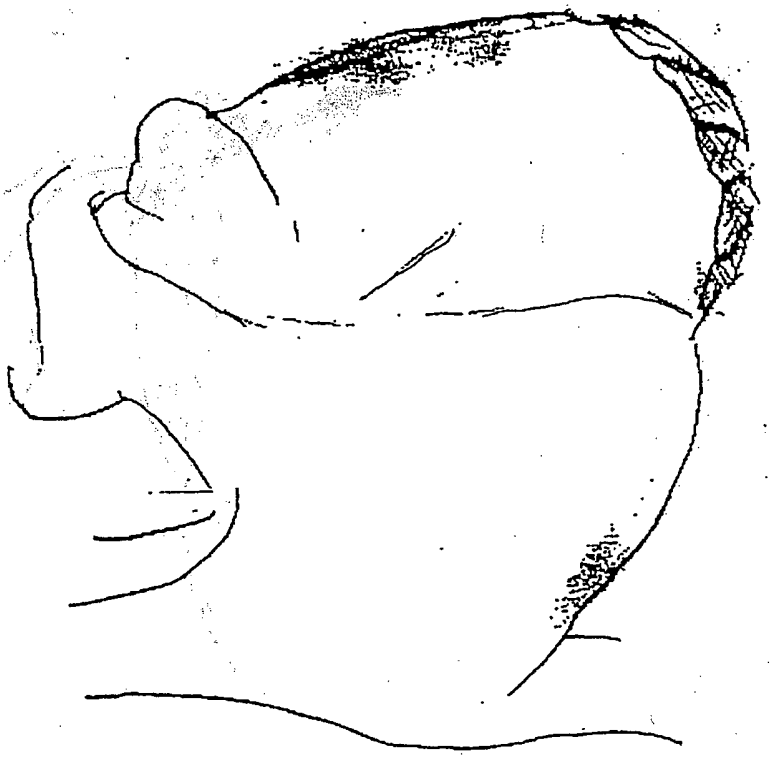
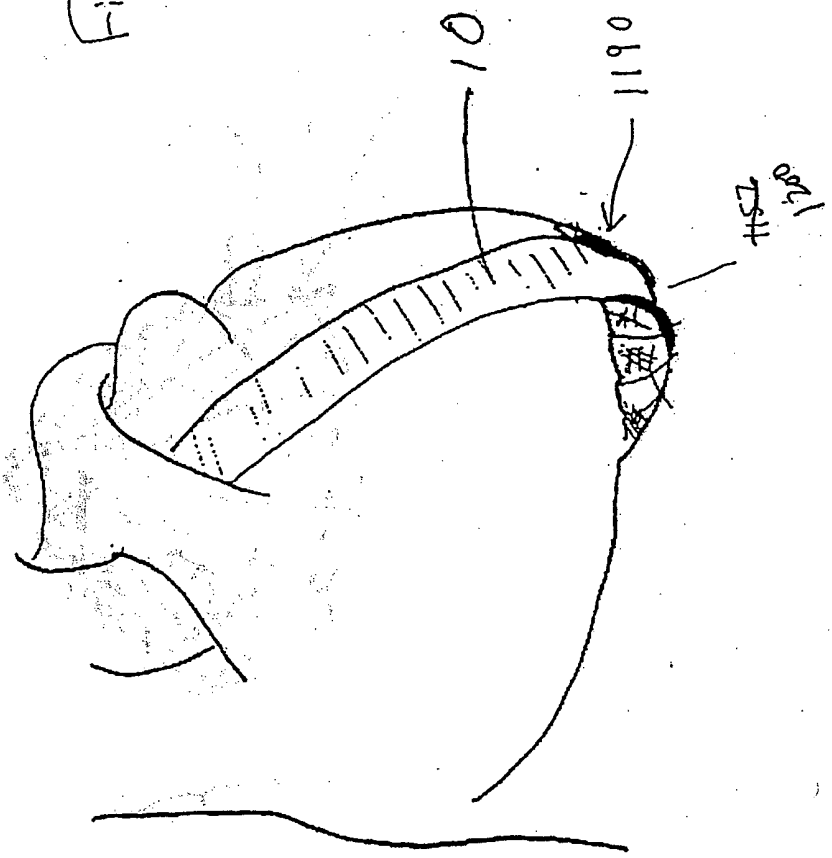


Fig. 12A



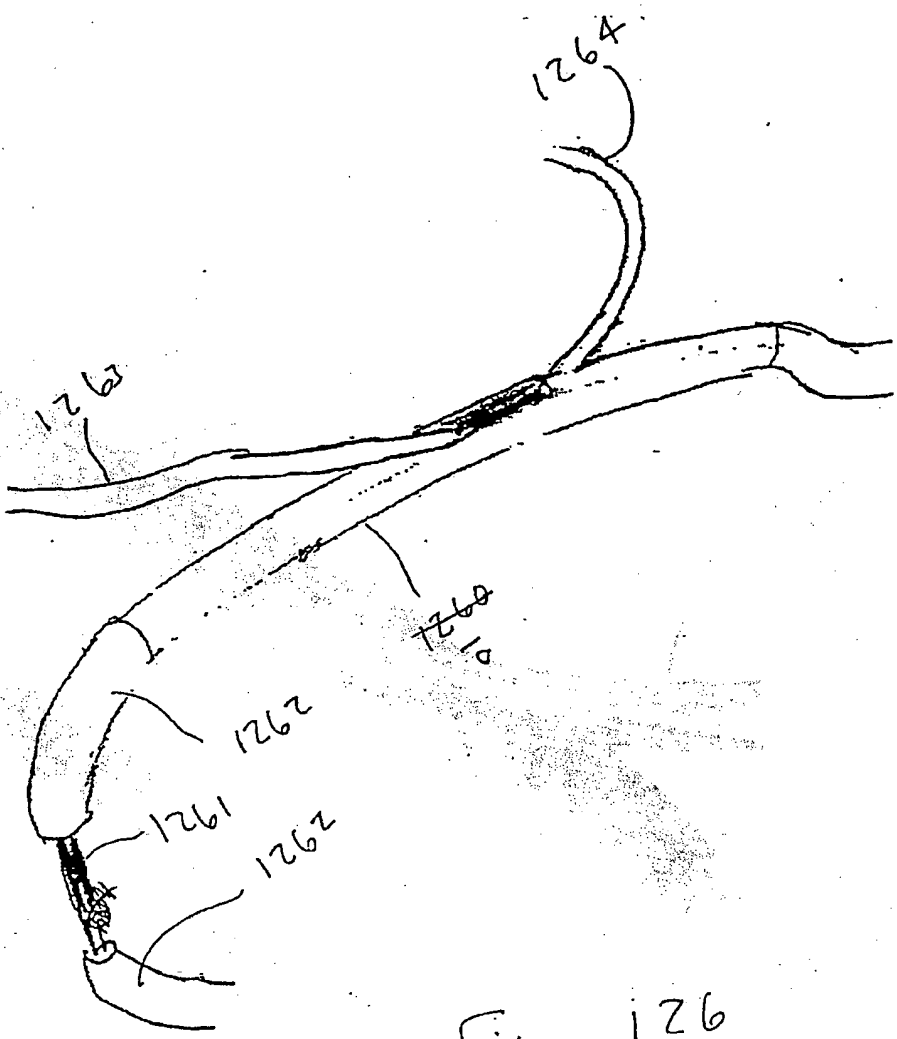


Fig. 126

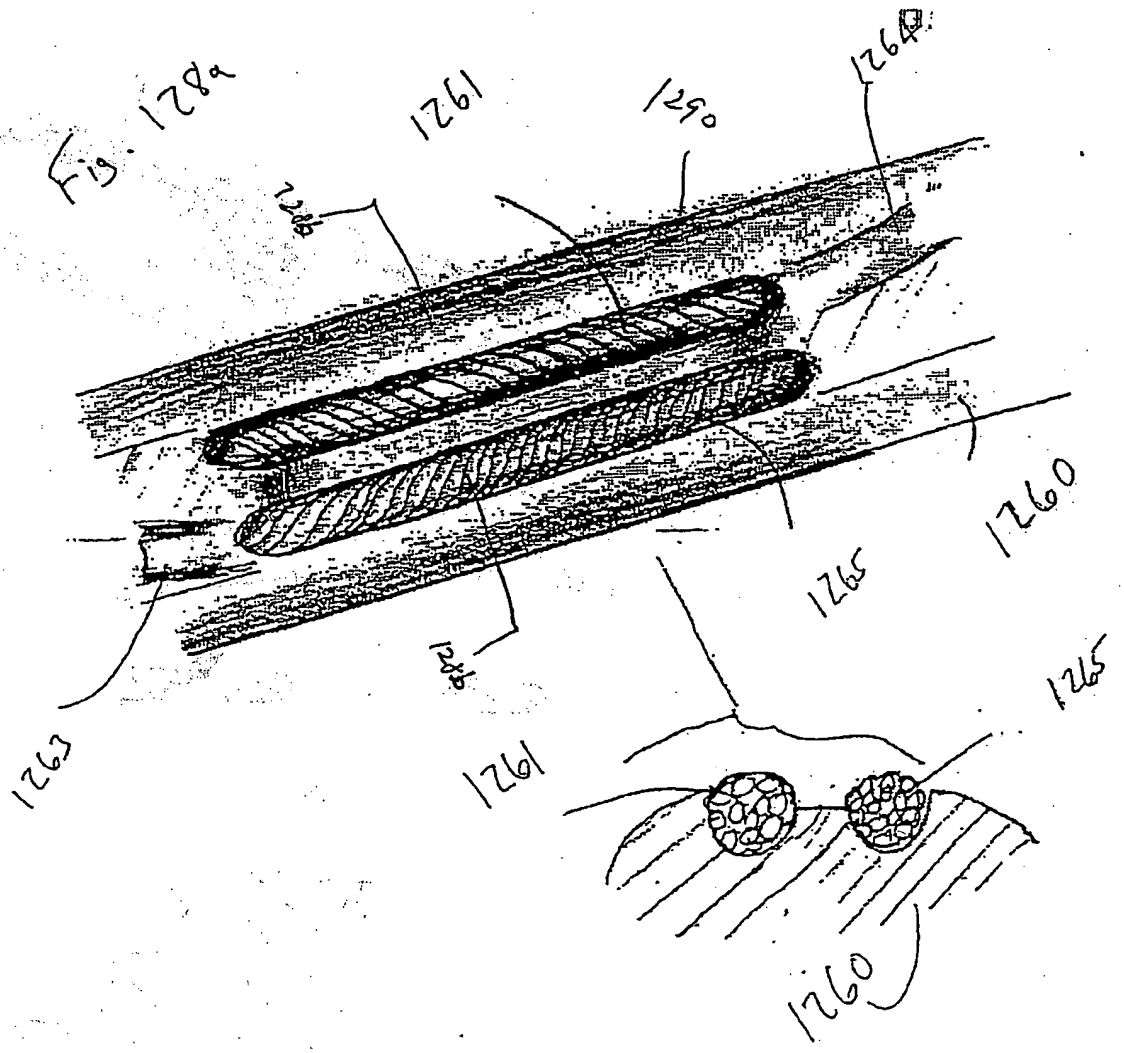


Fig. 128b

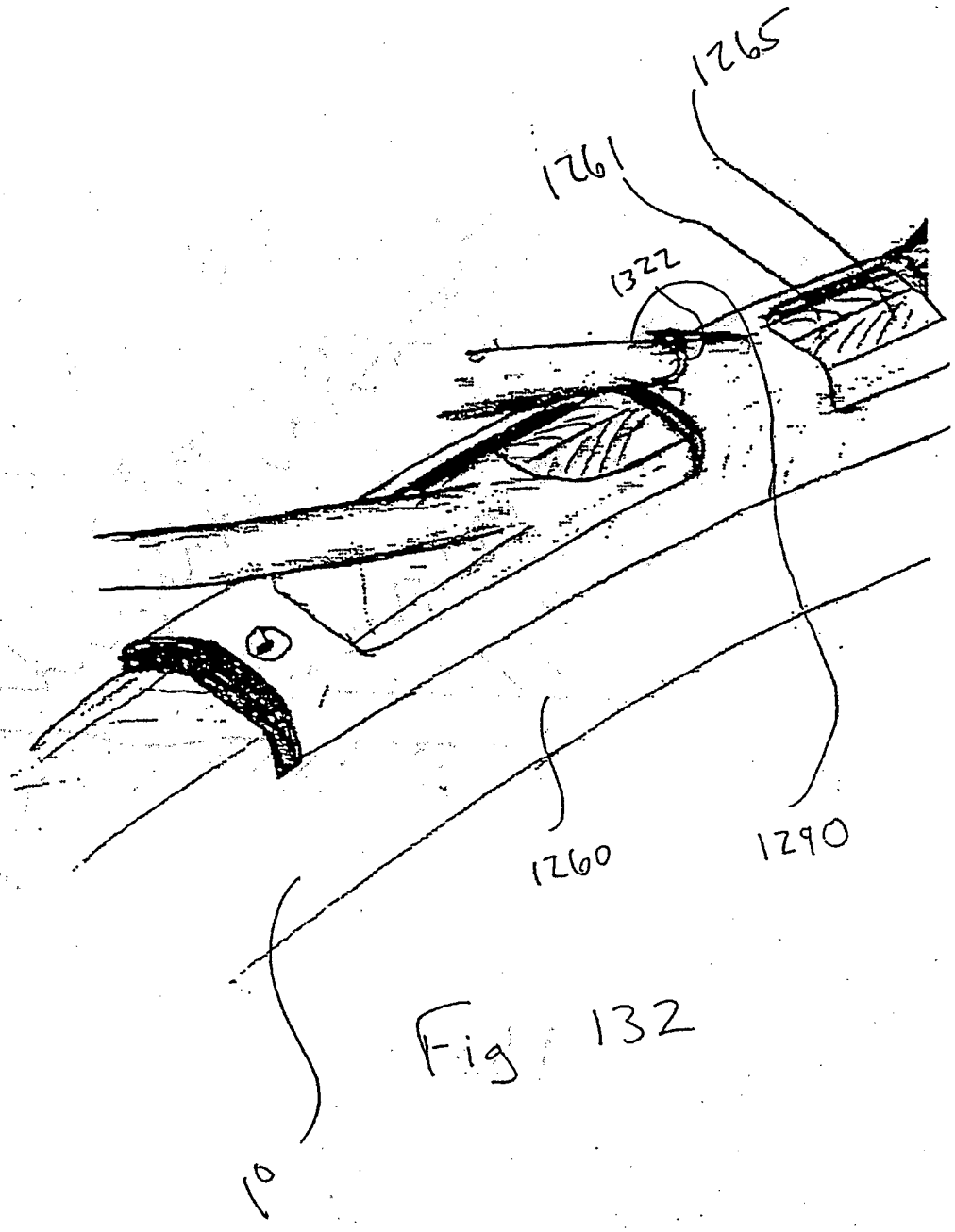


Fig. 132

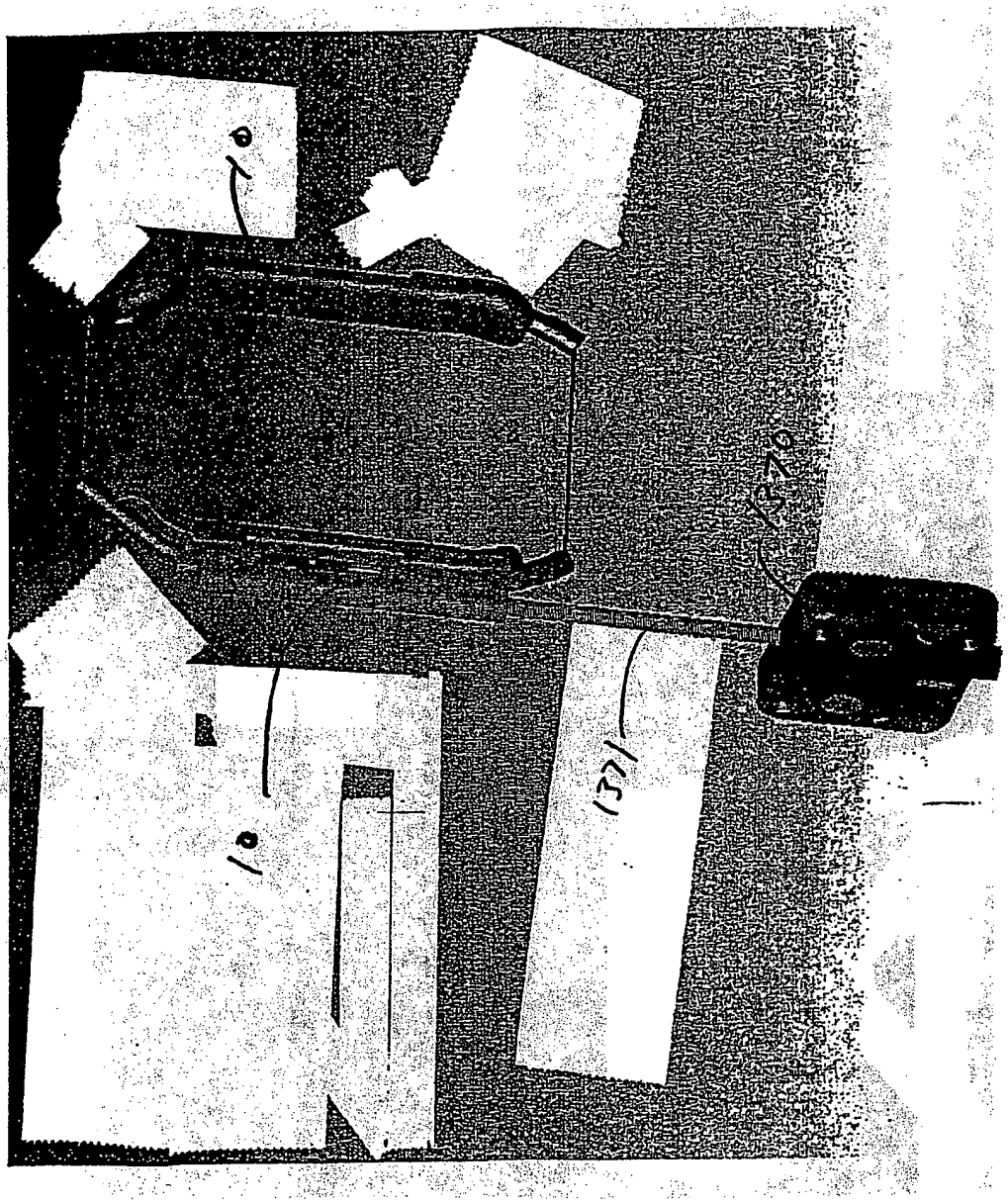


Fig. 134

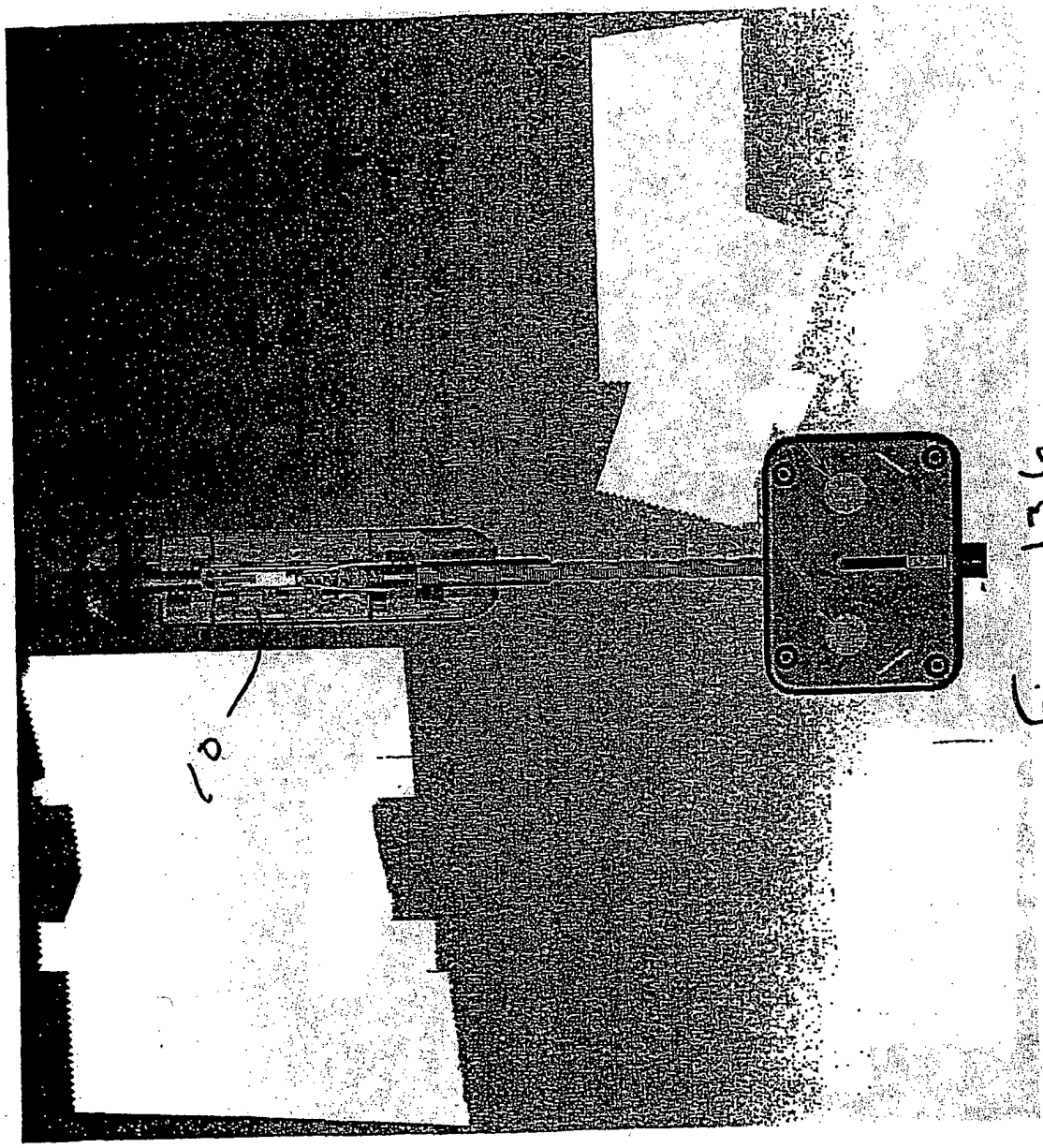


Fig. 139

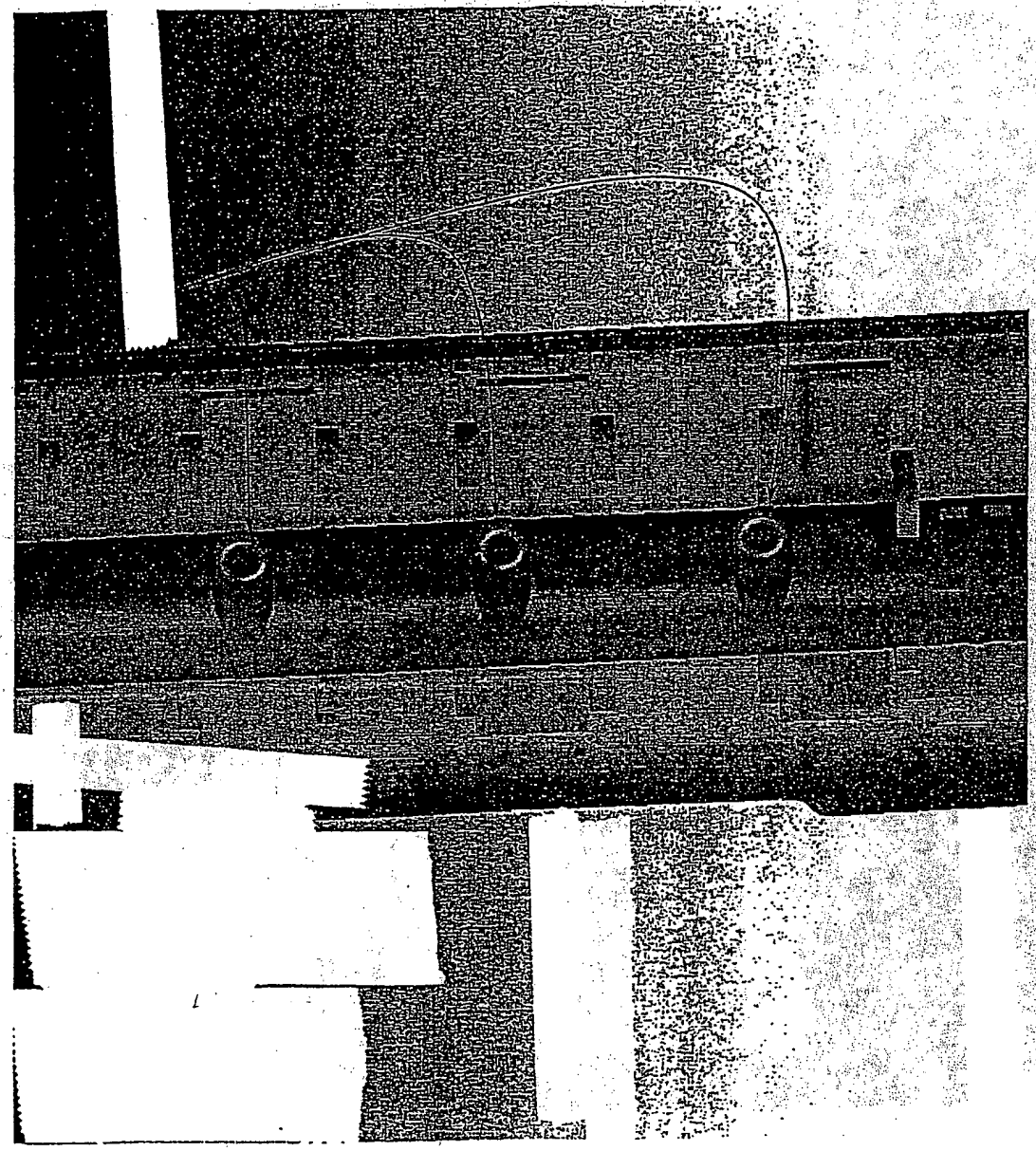


Fig. 38

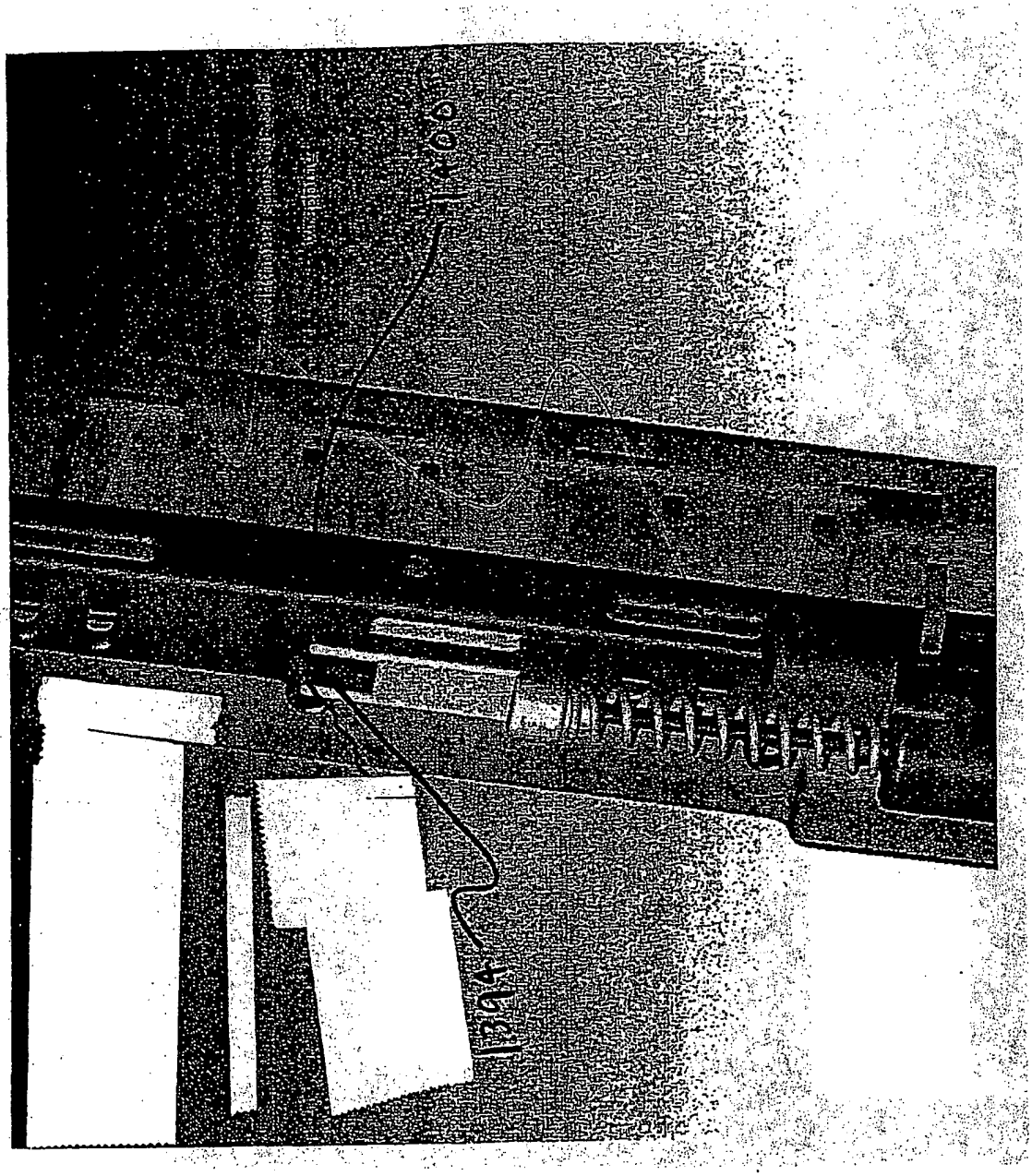


Fig. 140

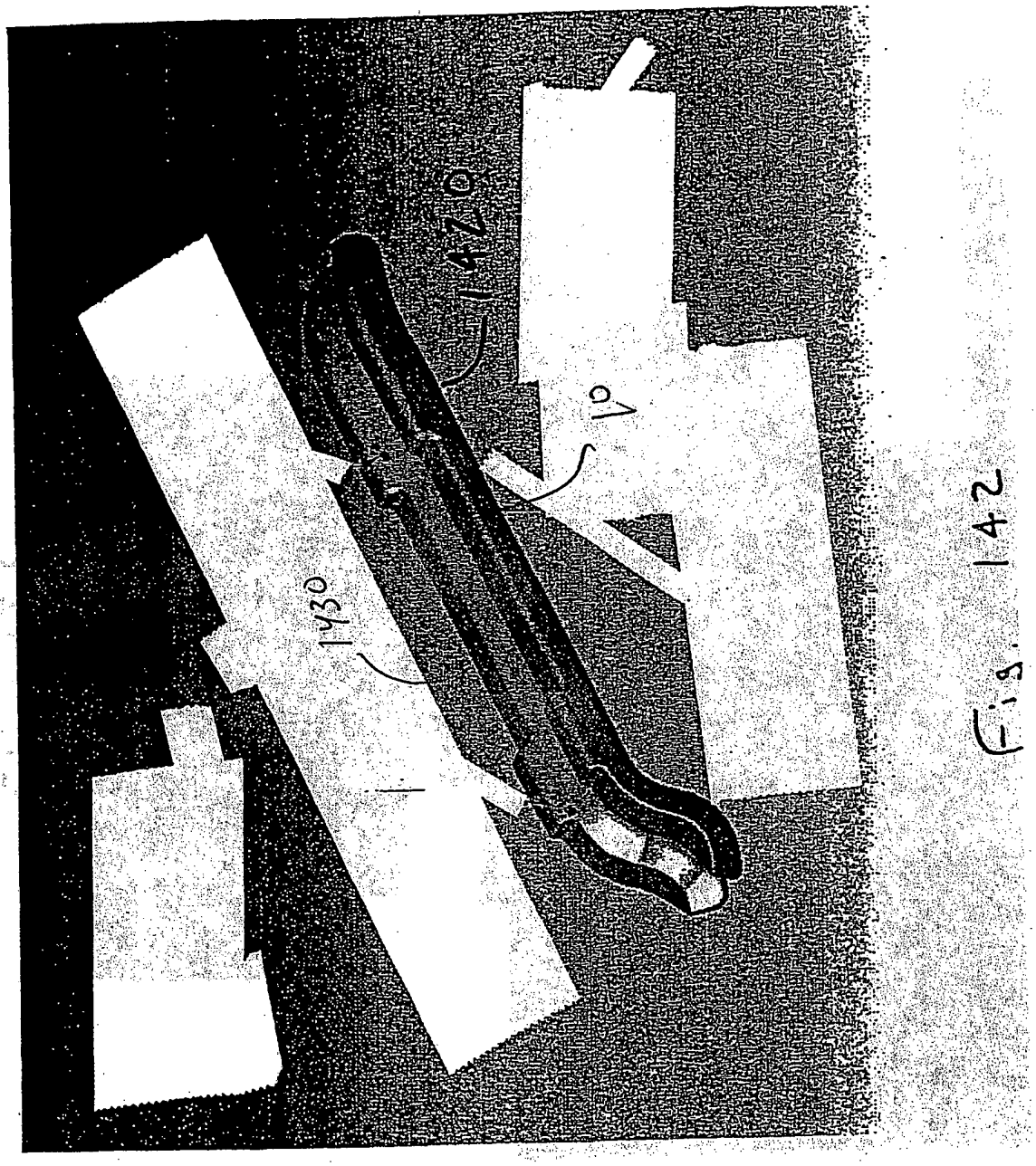


Fig. 142

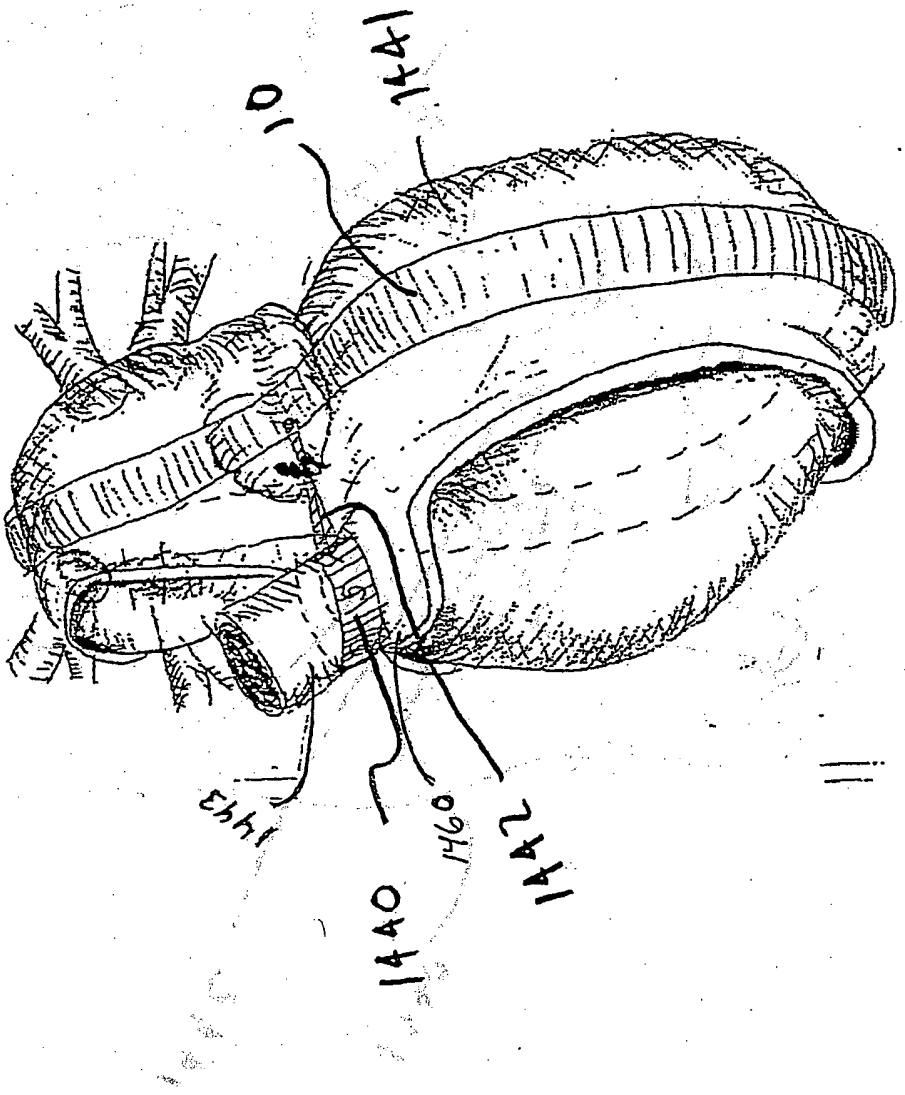


Fig. 144

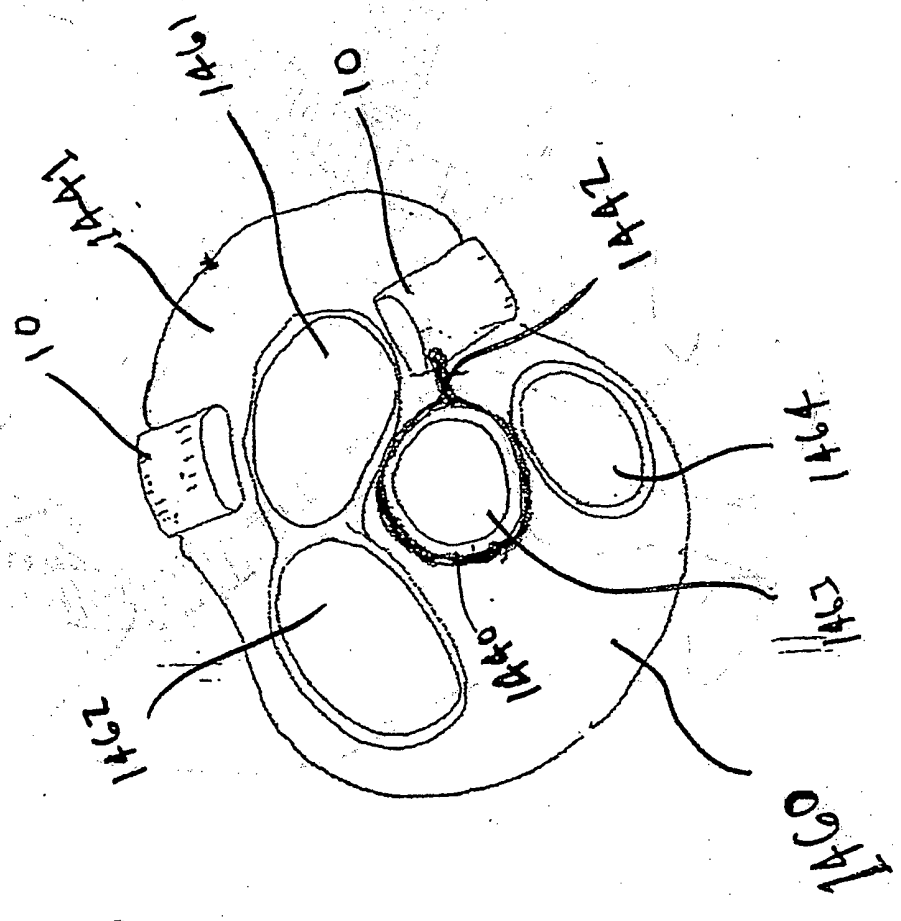


Fig. 146

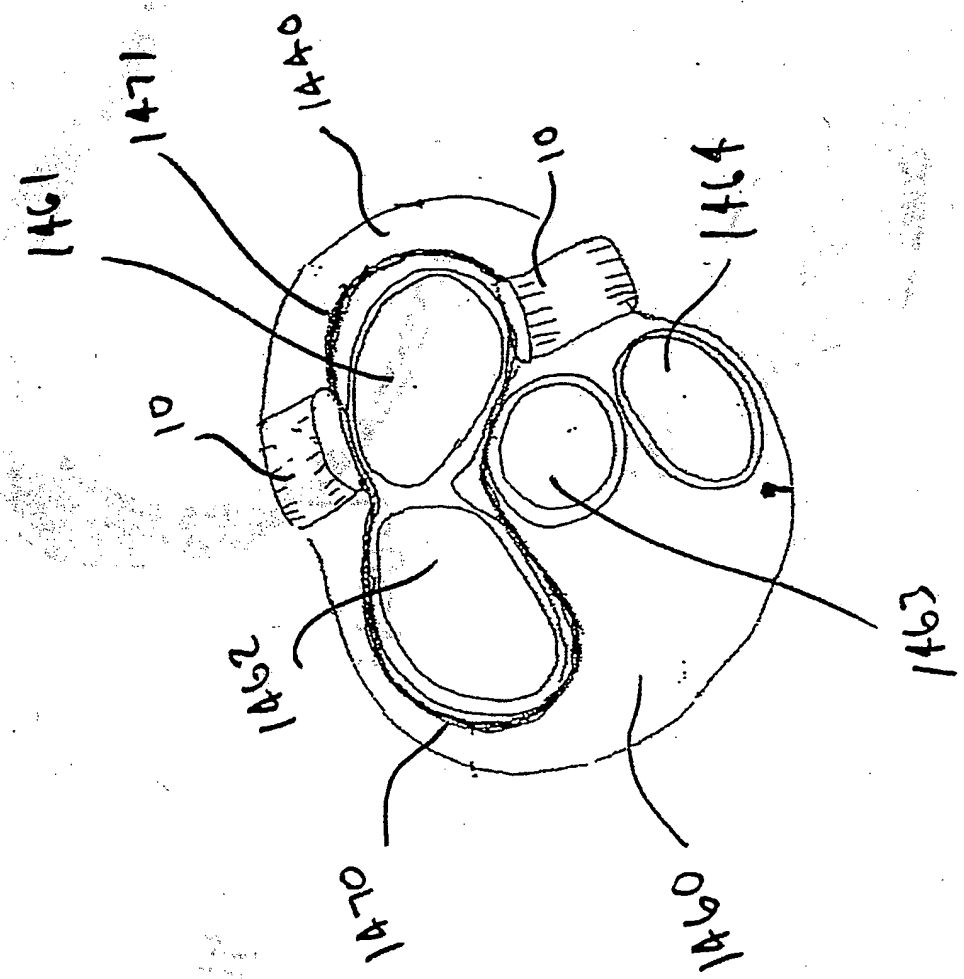


Fig 148

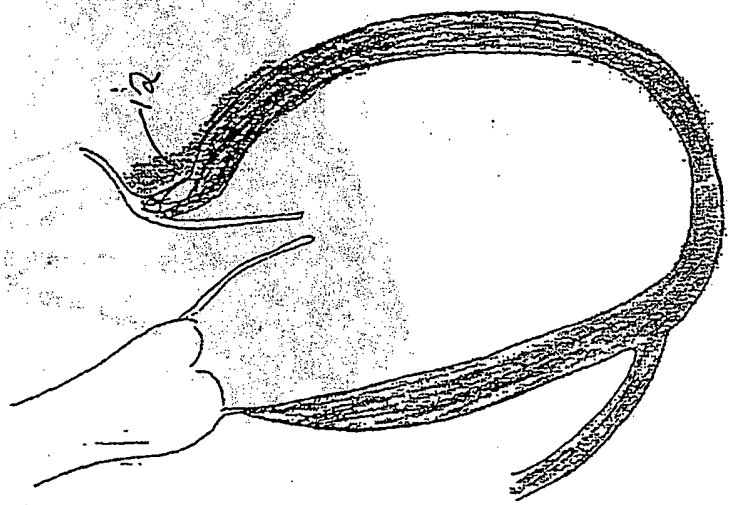


Fig 150

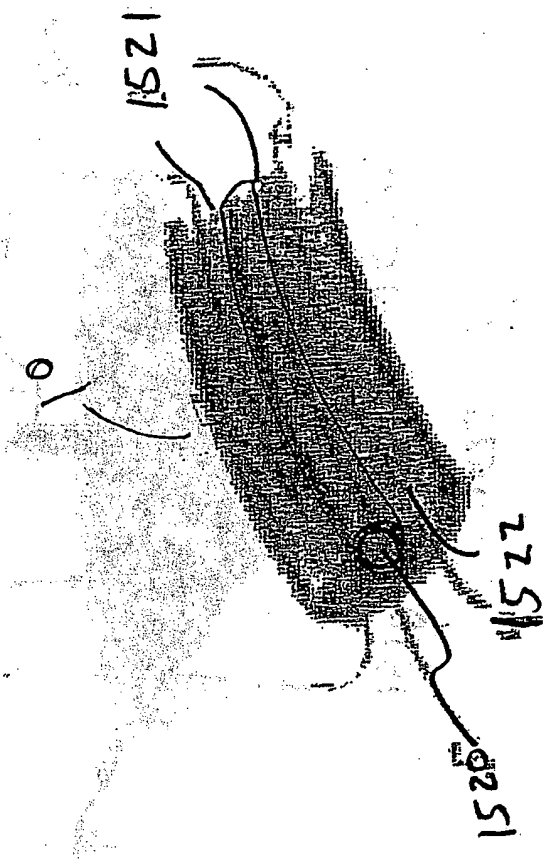


Fig. 152

Fig. 15A

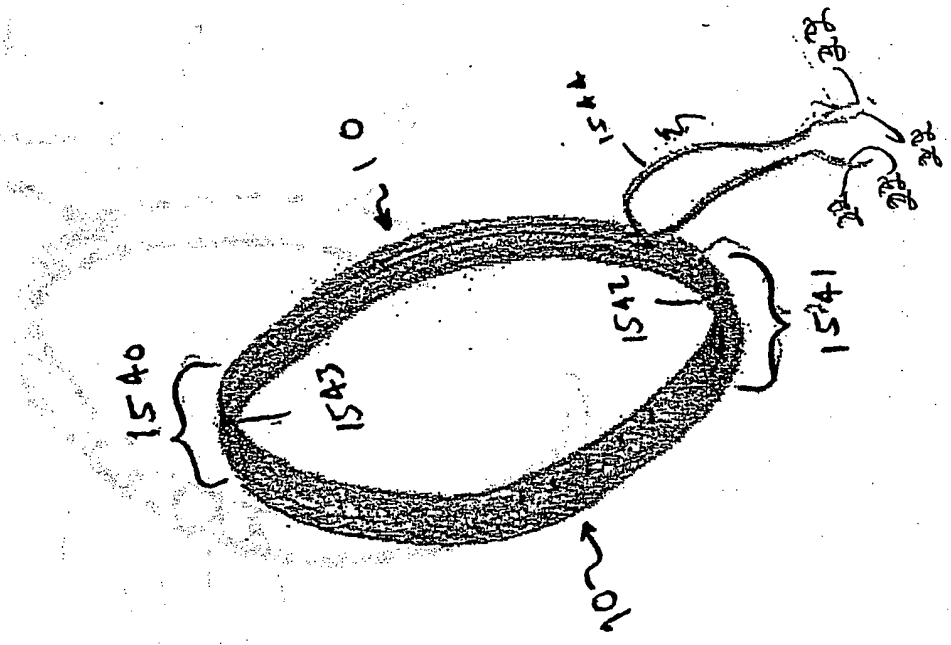


Fig. 15G

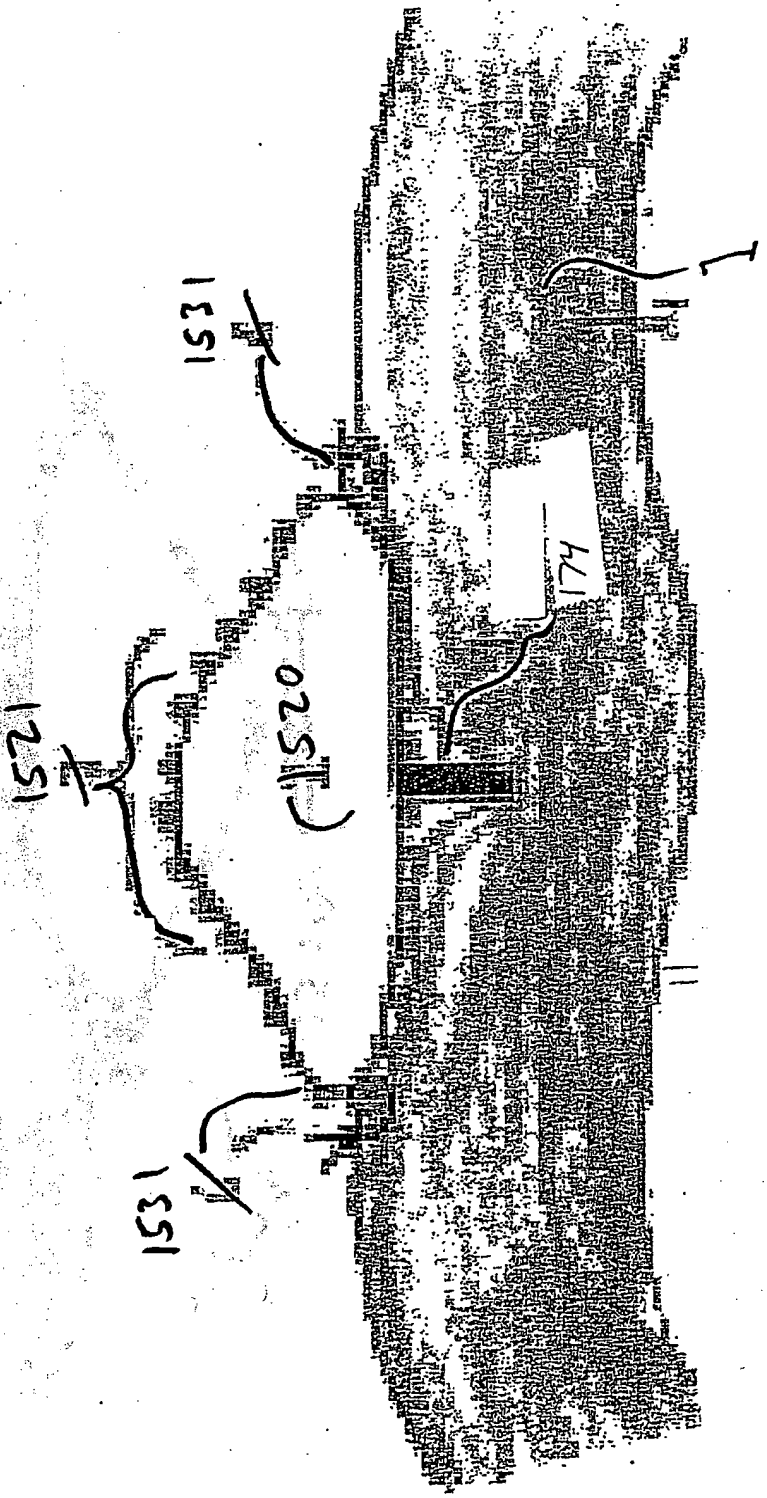


Fig. 158

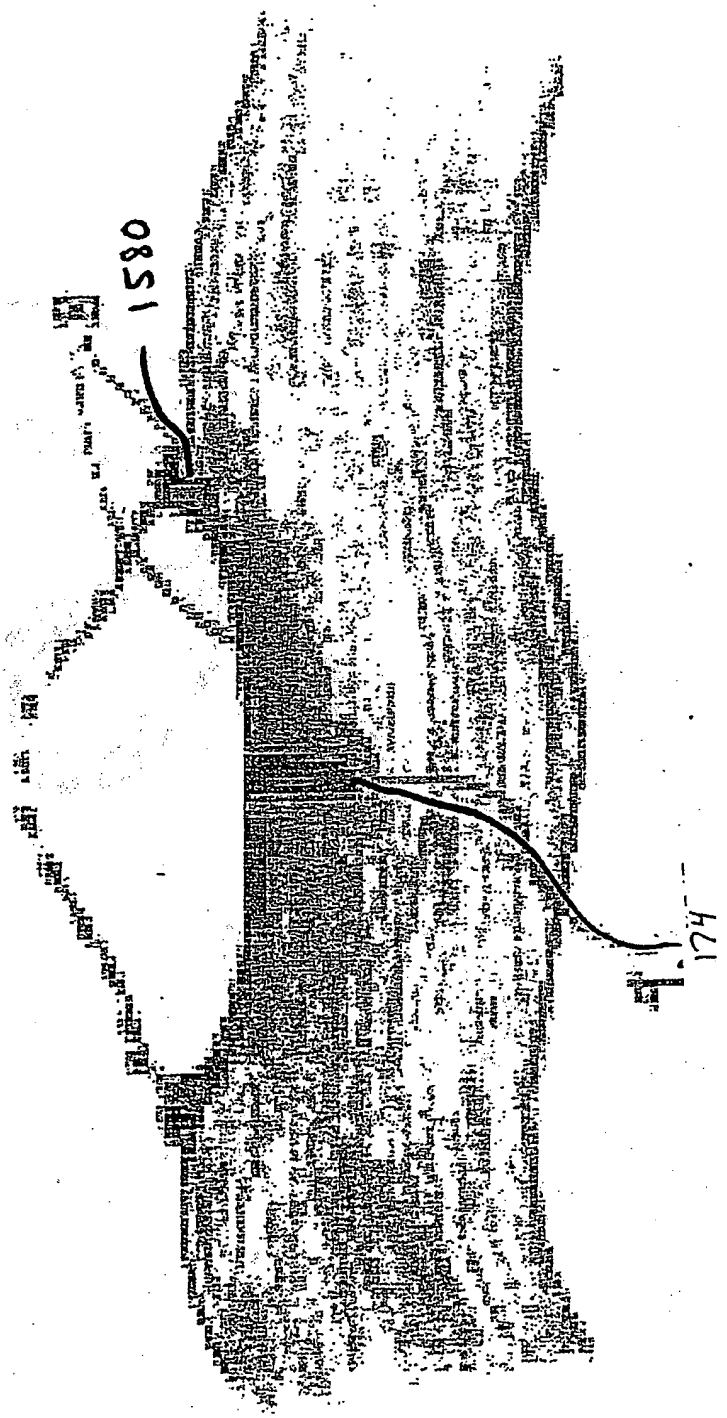


Fig. 160

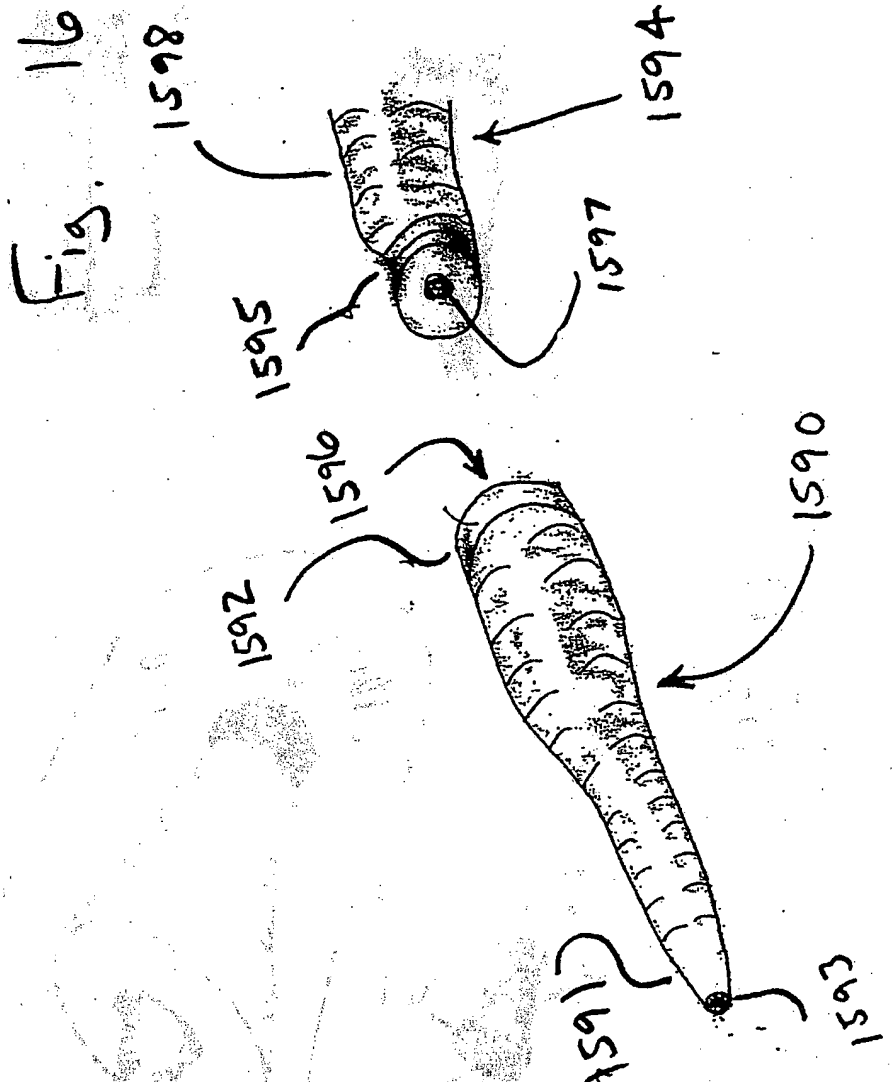


Fig. 162

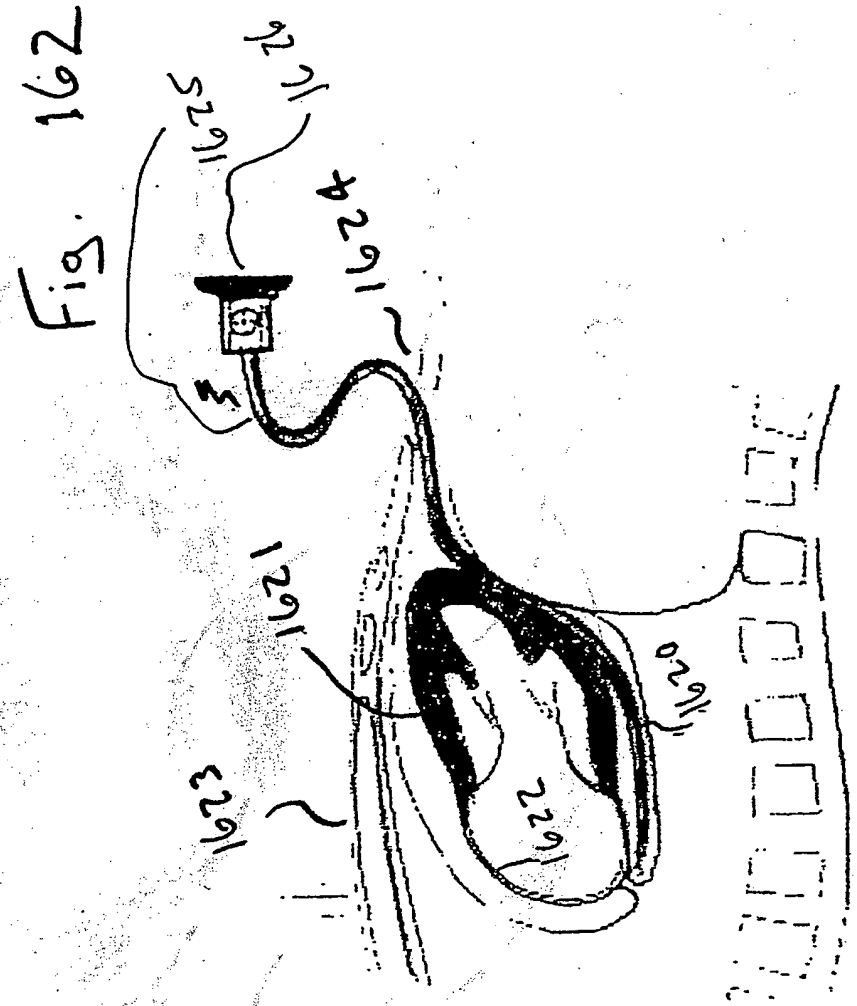


Fig. 164

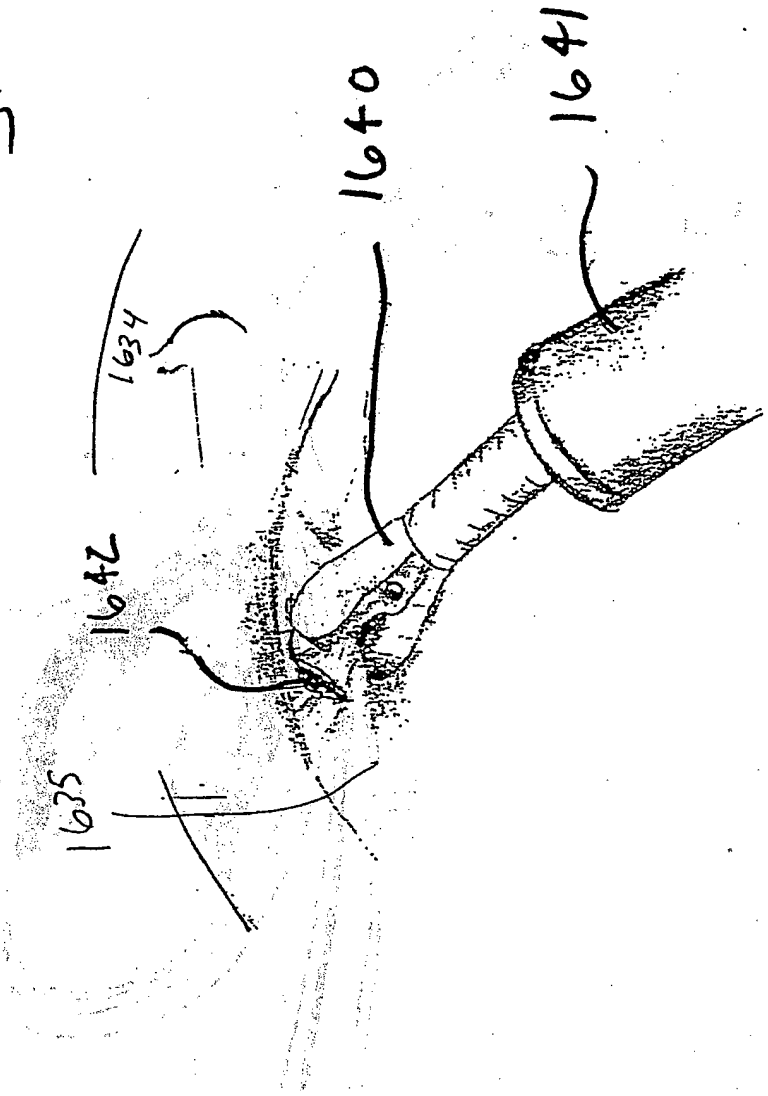


Fig. 166

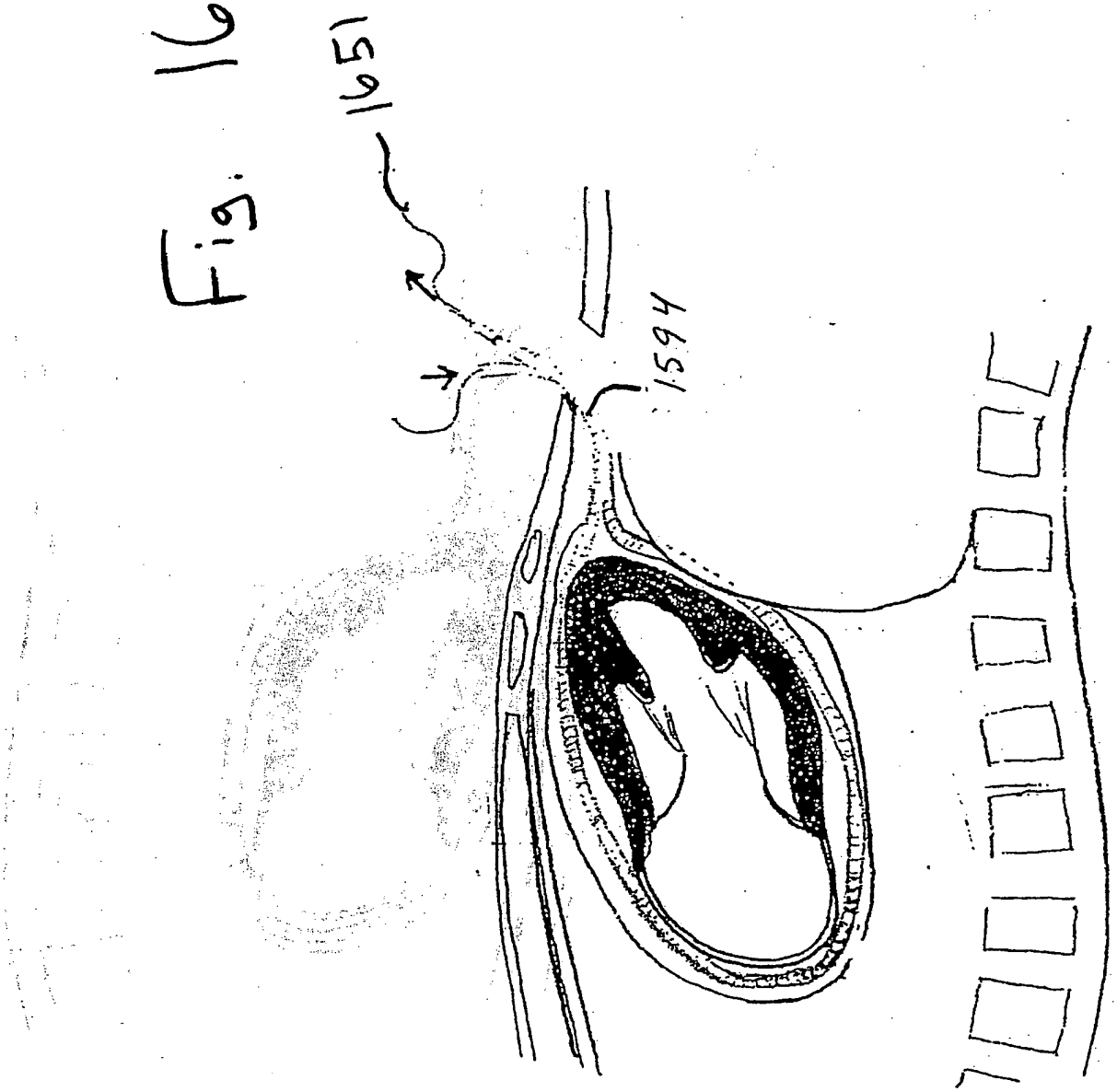


Fig. 168

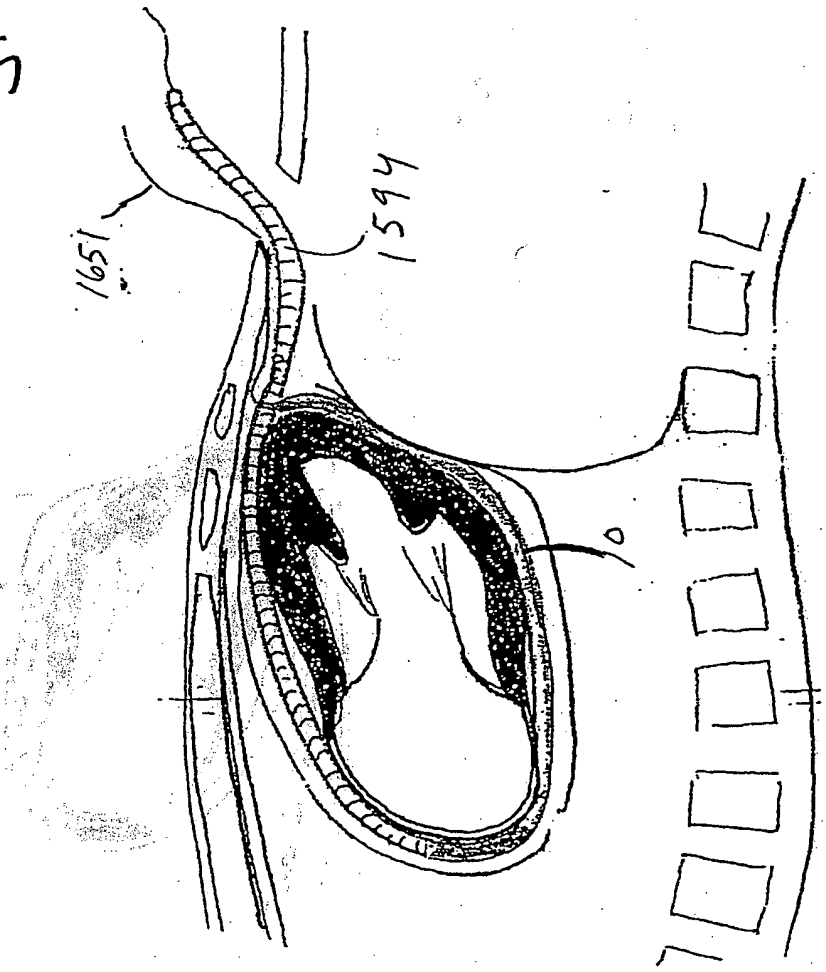
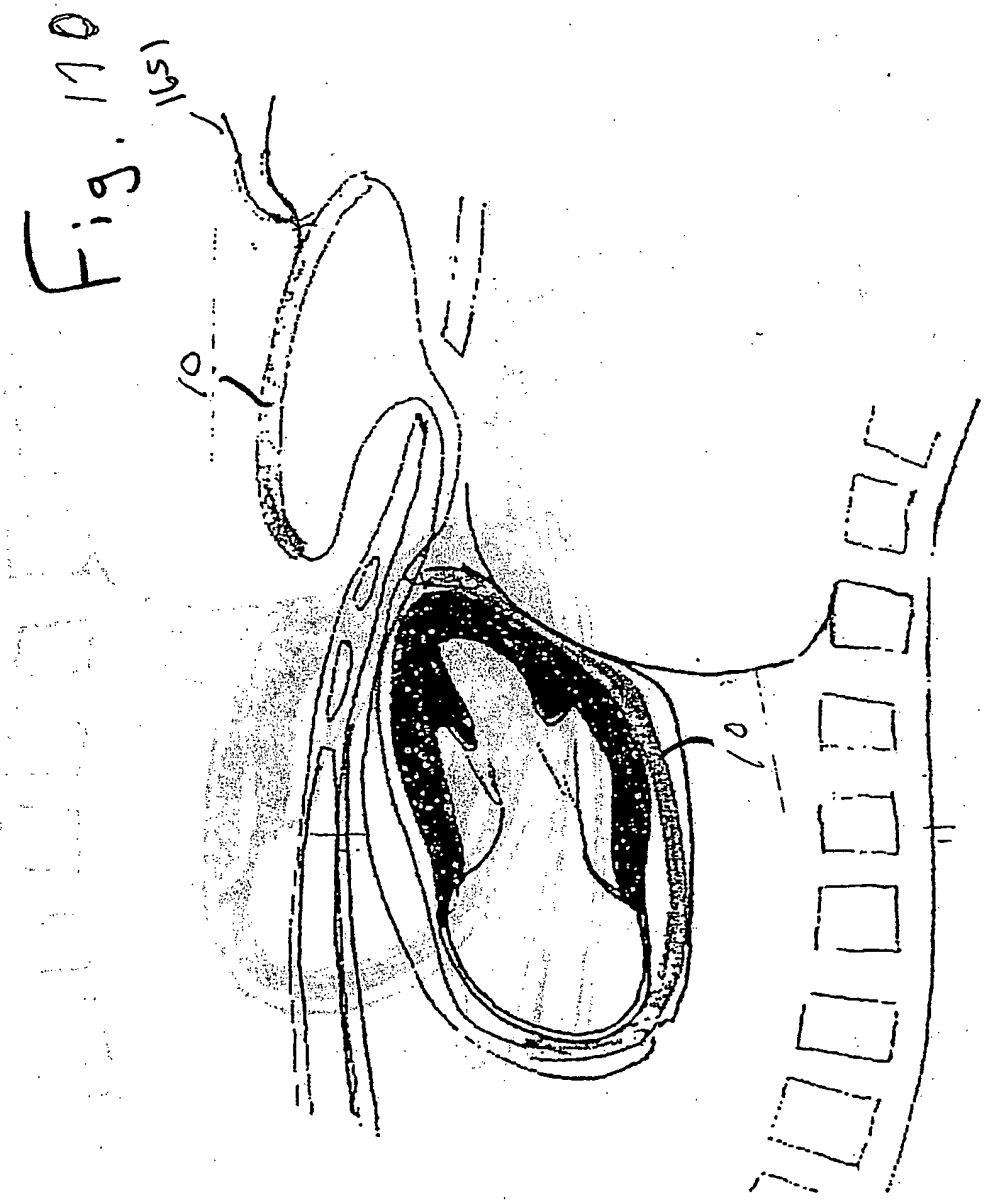


Fig. 11A



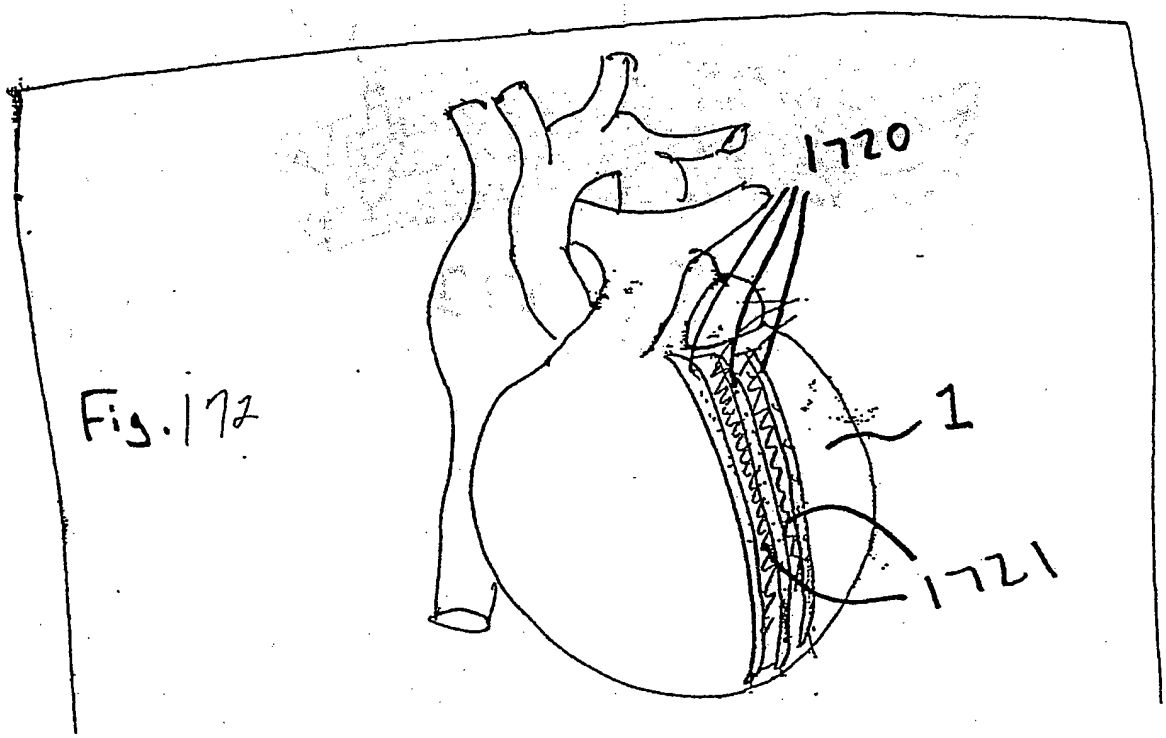


Fig. 172

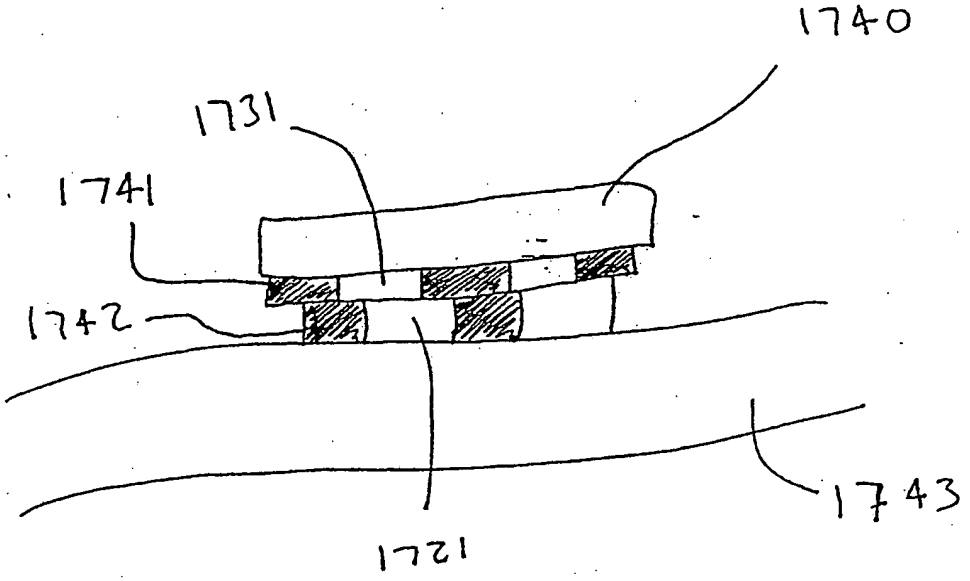


Fig. 174